# NOTICES OF FINAL RULEMAKING

The Administrative Procedure Act requires the publication of the final rules of the state's agencies. Final rules are those which have appeared in the *Register* first as proposed rules and have been through the formal rulemaking process including approval by the Governor's Regulatory Review Council or the Attorney General. The Secretary of State shall publish the notice along with the Preamble and the full text in the next available issue of the *Register* after the final rules have been submitted for filing and publication.

## NOTICE OF FINAL RULEMAKING

### TITLE 4. PROFESSIONS AND OCCUPATIONS

### CHAPTER 23. BOARD OF PHARMACY

[R07-349]

### PREAMBLE

**1. Sections Affected** — **Rulemaking Action**

| | |
|---|---|
| R4-23-110 | Amend |
| R4-23-605 | Amend |
| R4-23-607 | Amend |

**2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):**

Authorizing statutes: A.R.S. §§ 32-1904(A)(1) and 32-1904(B)(3)

Implementing statutes: A.R.S. §§ 32-1930, 32-1981, 32-1982, 32-1983, 32-1984, and 32-1985

**3. The effective date of the rules:**

December 1, 2007

**4. A list of all previous notices appearing in the *Register* addressing the proposed rules:**

Notice of Rulemaking Docket Opening, 12 A.A.R. 3074, August 25, 2006

Notice of Proposed Rulemaking 13 A.A.R. 822, March 16, 2007

**5. The name and address of agency personnel with whom persons may communicate regarding the rules:**

| | |
|---|---|
| Name: | Dean Wright, Prescription Monitoring Program Director |
| Address: | Board of Pharmacy<br>1700 W. Washington St., #250<br>Phoenix, AZ 85007 |
| Telephone: | (602) 771-2727 |
| Fax: | (602) 771-2749 |
| E-mail: | dwright@azpharmacy.gov |

**6. An explanation of the rules, including the agency's reasons for initiating the rules:**

During the 2005 legislative session, the Legislature passed a bill adding Article 3.1 (Regulation of Full Service Wholesale Permittees) to A.R.S. Title 32 (Professions and Occupations) Chapter 18 (Pharmacy). The new Article 3.1 contains five Sections: § 32-1981 (Definitions), § 32-1982 (Full service wholesale permittees; bonds; designated representatives; application), § 32-1983 (Restrictions on transactions), § 32-1984 (Pedigrees; electronic files), and § 32-1985(Injunctive relief). In order to implement the changes made by the 47th Legislature, the Board is amending R4-23-605 (Resident Drug Wholesaler Permit) and R4-23-607 (Nonresident Permits) to incorporate new requirements for designated representatives, bonds, fingerprints, pedigrees, and drug return and exchanges as specified in A.R.S. Article 3.1. A new subsection detailing requirements for returned, outdated, damaged, deteriorated, adulterated, misbranded, counterfeited, and contraband drugs will be added to R4-23-607 to bring the rules up to standards established in the National Association of Boards of Pharmacy (NABP) Model Rules.

The Board staff discovered that many licensees and permittees are not aware that precursor chemical and regulated chemical are defined in A.R.S. Title 13 (Criminal Code) Chapter 34 (Drug Offenses). The rulemaking will add a definition for "precursor chemical" and "regulated chemical" to R4-23-110 (Definitions), so the definitions of those

terms will be readily available to the Board's licensees and permittees. The rules will include format, style, and grammar necessary to comply with the current rules of the Secretary of State and Governor's Regulatory Review Council.

The Board believes that approval of these rules benefits the public and the pharmacy community by clearly establishing the standards for resident and nonresident drug wholesaler permittees.

**7. A reference to any study relevant to the rules that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rules, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:**

The agency did not review or rely on any study relevant to the rules.

**8. A showing of good cause why the rules are necessary to promote a statewide interest if the rules will diminish a previous grant of authority of a political subdivision of this state:**

Not applicable

**9. The summary of the economic, small business, and consumer impact:**

The amended rules will impact the Board, drug wholesalers, and the public. The amended rules' impact on the Board will be the usual rulemaking-related costs, which are minimal. The Board estimates the amended rules will have minimal to moderate economic impact on Board office operations through increased staff time to process drug wholesaler permit applications, including verifying the criminal records history check and issuing fingerprint clearances. The Board estimates the amended rules will have minimal economic impact on drug wholesalers. The amended rules will require a full-service drug wholesale permittee to submit a full set of fingerprints from the permittee's designated representative and a criminal history record check fee specified by and made payable to the Arizona Department of Public Safety. A person will pay about $12 to $15 to have a fingerprint card prepared by a local police department and the current fee for a federal and state criminal history record check is $29. The total cost for a criminal history record check will be between $41 and $44. The cost of preparing a fingerprint card and the DPS federal and state criminal history record check fee will have a minimal economic impact on full-service drug wholesalers and will help ensure that only people with clean records are allowed to oversee the operations of a full-service drug wholesale firm. The amended rules have no economic impact on the public.

The public, Board, and drug wholesalers benefit from rules that are clear, concise, and understandable. The amended rules benefit the public and the pharmacy community by clearly establishing the standards for resident and nonresident drug wholesaler permittees.

**10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):**

There are no substantial changes in the final rules from the proposed rules. Based on written and verbal comments received by the Board, the Board changed the time period in which a full-service or nonprescription drug wholesale permittee must notify the Board of changes involving the type of drugs sold or distributed, ownership, address, telephone number, name of business, manager, or designated representative from 24 hours to 10 days. This change occurred in R4-23-605(C) and R4-23-607(E). Because the reporting time period change is less burdensome on the regulated public, the Board feels the change is not substantial. The reporting time period change will make the reporting less onerous on public companies where changes occur at higher levels but do not filter down to the individual responsible for reporting to the Board for sometimes several days. This is not a public safety issue, and an increase in the reporting time period will benefit all of the regulated public with no potential for harm to the public. Based on written comment received by the Board, the Board made changes to R4-23-605(G)(1)(a)(iii), R4-23-605(G)(2)(a)(v) and (vii), R4-23-605(G)(2)(b)(v), R4-23-605(G)(3)(a)(iv) and (vi), R4-23-605(G)(3)(b)(v), R4-23-605(J)(7), R4-23-607(G)(1)(d), R4-23-607(G)(2)(d), R4-23-607(G)(3)(c) and (e), and R4-23-607(G)(4)(c) to correct a statute citation error. The proposed rule cited the definition of "authorized officer of the law" at A.R.S. § 32-1901(4), but the correct citation is A.R.S. § 32-1901(5). Based on verbal comment received by the Board and the fact that the words repeat the statutory requirement, the Board determined that the words "maintain a copy of each pedigree required by A.R.S. § 32-1984" are not necessary and removed R4-23-605(G)(2)(v), R4-23-605(G)(3)(iv), and R4-23-607(G)(3)(c). The subsections affected were renumbered. In a Notice of Final Rulemaking published in 13 A.A.R. 520, February 23, 2007, Section R4-23-607(A) was amended in the same manner that R4-23-607 was proposed to be amended in this rule package's Notice of Proposed Rulemaking. The final rule published on February 23, 2007 became effective on April 7, 2007. This final rule includes the language as amended on April 7, 2007. Based on written comment received by the Board stating that the language in R4-23-607(A)(3) implies that all nonresident permittees must have a pharmacist-in-charge licensed in Arizona. It was the Board's intent that only nonresident pharmacy permittees must have an Arizona licensed pharmacist-in-charge. To clarify the Board's intent, the final rule is changed to include the words "For a nonresident pharmacy," before the word "employing" in R4-23-607(A)(3). There are minor changes to style, format, grammar, and punctuation requested by G.R.R.C. staff.

**11. A summary of the comments made regarding the rules and the agency response to them:**

A public hearing was held April 23, 2007. Daniel Bellingham and Susan Pilch representing the Healthcare Distribution Management Association, Martha Russell representing Cardinal Health, and Steve Duffy attended the public hearing. Susan Pilch provided oral comments during the hearing. The Board received written comment from the Arizona Community Pharmacy Committee voicing support for the rulemaking. The Board also received written comments from Merrill Jacobs of the Pharmaceutical Research and Manufacturers of America (PhRMA), Martha Russell,

Cardinal Health, and Susan Pilch, Healthcare Distribution Management Association (HDMA). The comments from PhRMA and HDMA centered on the pedigree requirements and the meaning of "normal distribution channel." Both commenters wanted the Board to make changes to the pedigree requirements and the definition of "normal distribution channel." HDMA made numerous comments about how other states have changed their definition of "normal distribution channel" over the last few years, and how the Board should also make similar changes. HDMA requested that the Board not go forward with the pedigree rules until the statutory definition of "normal distribution channel" could be changed. The Board staff pointed out that the pedigree requirements and the definition of "normal distribution channel" are in statute and cannot be changed by the Board. The rules do not set or expand the pedigree requirements that are set in statute, so the Board does not feel there is a reason to hold the rulemaking. Both parties agreed that they would need to seek changes in the legislature in 2008. The Board agreed to remove the language in R4-23-605(G)(2)(v), R4-23-605(G)3)(iv), and R4-23-607(G)(3)(c) that states "maintain a copy of each pedigree required by A.R.S. § 32-1984," because the language is not necessary and actually repeats the statutory requirement.

Martha Russell, Cardinal Healthcare commented that the changes to R4-23-607(A) imply that all nonresident permittees must have an Arizona licensed pharmacist-in-charge. The staff explained that was not the Board's intent. Since that language had actually gone into effect on April 7, 2007 in a different rule package and the implication was not noticed at that time, the Board has added the words "For a nonresident pharmacy" before the word "employing" in R4-23-607(A)(3) to specify that only nonresident pharmacies must employ an Arizona licensed pharmacist-in-charge. Ms. Russell had further comment regarding R4-23-605(C) and R4-23-607(E) that deal with the time period for notification to the Board of a change in status of a resident or nonresident wholesaler. Ms. Russell stated that her members would like to see this period extended to 10 days, which is the time period that many other states require for notification. Ms. Russell commented that 24 hours is not much time when dealing with large organizations where unexpected changes in staffing may take a day or more just to get to the proper reporting person. The Board staff agreed to make the change to 10 days for notifications. Ms. Russell commented that she found a citation error regarding the definition of "authorized officer of the law" that is used in numerous subsections within R4-23-605 and R4-23-607. The citation in the proposed rule was A.R.S. § 32-1901(4), but the correct citation is A.R.S. § 32-1901(5). The Board staff thanked Ms. Russell for catching the error. The final rule changes the citations to A.R.S. § 32-1901(4) to A.R.S. § 32-1901(5) in the following: R4-23-605(G)(1)(a)(iii), R4-23-605(G)(2)(a)(v) and (vii), R4-23-605(G)(2)(b)(v), R4-23-605(G)(3)(a)(iv) and (vi), R4-23-605(G)(3)(b)(v), R4-23-605(J)(7), R4-23-607(G)(1)(d), R4-23-607(G)(2)(d), R4-23-607(G)(3)(c) and (e), and R4-23-607(G)(4)(c).

**12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:**

Not applicable

**13. Incorporations by reference and their location in the rules:**

None

**14. Were these rules previously approved as emergency rules?**

No

**15. The full text of the rules follows:**

## TITLE 4. PROFESSIONS AND OCCUPATIONS

## CHAPTER 23. BOARD OF PHARMACY

### ARTICLE 1. ADMINISTRATION

Section
R4-23-110. Definitions

### ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

Section
R4-23-605. Resident Drug Wholesaler Permit
R4-23-607. Nonresident Permits

### ARTICLE 1. ADMINISTRATION

**R4-23-110. Definitions**

In addition to definitions in A.R.S. § 32-1901, the following definitions apply to A.A.C. Title 4 Chapter 23:

"Active ingredient" No change

"Alternate physician" No change

"Approved course in pharmacy law" No change

"Approved Provider" No change
"Authentication of product history" No change
"Automated storage and distribution system" No change
"Batch" No change
"Beyond-use date" No change
"Biological safety cabinet" No change
"Care-giver" No change
"Community pharmacy" No change
"Component" No change
"Compounding and dispensing counter" No change
"Computer system" No change
"Computer system audit" No change
"Contact hour" No change
"Container" No change
"Continuing education" No change
"Continuing education activity" No change
"Continuing education unit" or "CEU" No change
"Correctional facility" No change
"CRT" No change
"Current good compounding practices" No change
"Current good manufacturing practice" No change
"Cytotoxic" No change
"Day" No change
"DEA" No change
"Delinquent license" No change
"Dietary supplement" No change
"Digital signature" No change
"Dispensing pharmacist" No change
"Drug sample" No change
"Drug therapy management" No change
"Drug therapy management agreement" No change
"Electronic signature" No change
"Eligible patient" No change
"Extreme emergency" No change
"FDA" No change
"Immediate notice" No change
"Inactive ingredient" No change
"Internal test assessment" No change
"ISO Class 5 environment" No change
"ISO Class 7 environment" No change
"Limited-service correctional pharmacy" No change
"Limited-service long-term care pharmacy" No change
"Limited-service mail-order pharmacy" No change
"Limited-service nuclear pharmacy" No change
"Limited-service pharmacy permittee" No change
"Limited-service sterile pharmaceutical products pharmacy" No change
"Long-term care consultant pharmacist" No change

"Long-term care facility" or "LTCF" No change
"Lot" No change
"Lot number" or "control number" No change
"Materials approval unit" No change
"Mechanical counting device for a drug in solid, oral dosage form" No change
"Mechanical storage and counting device for a drug in solid, oral dosage form" No change
"Mediated instruction" No change
"MPJE" No change
"NABP" No change
"NABPLEX" No change
"NAPLEX" No change
"Order" No change
"Other designated personnel" No change
"Outpatient" No change
"Outpatient setting" No change
"Patient profile" No change
"Pharmaceutical patient care services" No change
"Pharmaceutical product" No change
"Pharmacist-administered immunizations training program" No change
"Pharmacy counter working area" No change
"Pharmacy law continuing education" No change
"Pharmacy permittee" No change
"Precursor chemical" means a precursor chemical I as defined in A.R.S. § 13-3401(26) and a precursor chemical II as defined in A.R.S. § 13-3401(27).
"Prepackaged drug" No change
"Prep area" No change
"Proprietor" No change
"Provider pharmacy" No change
"Radiopharmaceutical" No change
"Radiopharmaceutical quality assurance" No change
"Radiopharmaceutical services" No change
"Red C stamp" No change
"Refill" No change
"Regulated chemical" means the same as in A.R.S. § 13-3401(30).
"Remodel" No change
"Remote drug storage area" No change
"Resident" No change
"Responsible person" No change
"Score transfer" No change
"Security paper" No change
"Shared order filling" No change
"Shared order processing" No change
"Shared services" No change
"Sight-readable" No change
"Single-drug audit" No change
"Single-drug usage report" No change
"Standard-risk sterile pharmaceutical product" No change

"Sterile pharmaceutical product" No change

"Strength" No change

"Substantial-risk sterile pharmaceutical product" No change

"Supervision" No change

"Supervisory physician" No change

"Supplying" No change

"Support personnel" No change

"Transfill" No change

"Verified signature" or "signature verifying" No change

"Wholesale distribution" No change

"Wholesale distributor" No change

## ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

**R4-23-605. Resident Drug Wholesaler Permit**

**A**. Permit. A person shall not operate a business or firm for the wholesale distribution of any drug, device, precursor chemical, or regulated chemical without a current Board-issued full-service or nonprescription drug wholesale permit.

**B.** Application.

1. To obtain a permit to operate a full-service or nonprescription drug wholesale firm in Arizona, a person shall submit a completed application on a form furnished by the Board that includes:
   a. ~~The type of~~ Whether the application is for a full-service or nonprescription drug wholesale permit;
   b. Business name, address, mailing address, if different, telephone number, and facsimile number;
   c. Owner's name, if corporation or partnership, officers or partners, including address and title, and any other trade or business names used;
   d. Whether the owner, corporation, or partnership has conducted a similar business in any other jurisdiction and if so, indicate under what name and location;
   e. Whether the owner, any officer or active partner has ever been convicted of an offense involving moral turpitude, a felony offense, or any drug-related offense or has any currently pending felony or drug-related charges, and if so, indicate charge, conviction date, jurisdiction, and location;
   f. Whether the owner~~,~~ or any officer or active partner has ever been denied a drug wholesale permit in this state or any other jurisdiction, and if so, indicate where and when;
   g. For a full-service drug wholesale firm:
      i. The designated representative's name, address, and emergency telephone number;
      ii. Documentation that the designated representative meets the requirements of A.R.S. § 32-1982(B) and the following as specified in A.R.S. § 32-1982(C):
         (1) A full set of fingerprints from the designated representative; and
         (2) The state and federal criminal history record check fee specified by and made payable to the Arizona State Department of Public Safety by money order, certified check, or bank draft; and
      iii. A $100,000 bond as specified in A.R.S. § 32-1982(D) submitted on a form supplied by the Board;
   ~~g.~~h. The type of drugs, whether nonprescription, prescription-only, controlled substances, human, or veterinary, the applicant will distribute;
   ~~h.~~i. Plans or construction drawings showing facility size and security ~~adequate~~ for the proposed business;
   ~~i.~~j. Documentation of compliance with local zoning laws;
   ~~j.~~k. ~~Manager's or responsible person's~~ For a nonprescription drug wholesale firm, the manager's or designated representative's name, address, emergency telephone number, and ~~resume~~ resumé indicating educational or experiential qualifications related to drug wholesale operation;
   ~~k.~~l. For an application submitted because of ownership change, the former owner's name and business name, if different;
   ~~l.~~m. Date signed, and applicant's, corporate officer's, partner's, manager's, or ~~responsible person's~~ designated representative's verified signature and title; and
   ~~m.~~n. Fee specified in R4-23-205.
2. Before issuing a full-service or nonprescription drug wholesale permit, the Board shall:
   a. Receive and approve a completed permit application;
   b. Interview the applicant and the ~~responsible person~~ designated representative, if different from the applicant, at a Board meeting; ~~and~~
   c. Receive a satisfactory compliance inspection report on the facility from a Board compliance officer; and
   d. For a full-service drug wholesale permit, issue a fingerprint clearance to a qualified designated representative, as specified in subsection (L). If the fingerprint clearance of a designated representative for a full-service drug

wholesale permit applicant is denied, the full-service drug wholesale permit applicant shall appoint another designated representative and submit the documentation, fingerprints, and fee required in subsection (B)(1)(g)(ii).

**C.** Notification. A resident full-service or nonprescription drug wholesale permittee shall notify the Board of changes involving the type of drugs sold or distributed, ownership, address, telephone number, name of business, or manager~~,~~ or ~~responsible person~~ designated representative, including the manager's or ~~responsible person's~~ designated representative's telephone number.

1. The resident full-service or nonprescription drug wholesale permittee shall submit a written notice via mail, fax, or e-mail to the Executive Director within ~~24 hours~~ 10 days of the change, except any change of ownership requires that the resident full-service or nonprescription drug wholesale permittee comply with subsection (D).
2. For a change of designated representative, a resident full-service drug wholesale permittee shall submit the documentation, fingerprints, and fee required in subsection (B)(1)(g)(ii). If the fingerprint clearance of a designated representative for a full-service drug wholesale permit applicant is denied, the full-service drug wholesale permit applicant shall appoint another designated representative and submit the documentation, fingerprints, and fee required in subsection (B)(1)(g)(ii).

**D.** Change of ownership. Before a change of ownership occurs that involves changes of stock ownership of more than 30% of the voting stock of a corporation or an existing and continuing corporation that is not actively traded on any securities market or over-the-counter market, the prospective owner shall submit the application packet described under subsection ~~R4-23-605~~(B).

**E.** Before an existing resident full-service or nonprescription drug wholesaler permittee relocates, the resident full-service or nonprescription drug wholesale permittee shall submit the application packet described under subsection ~~R4-23-605~~(B), excluding the fee. The facility at the new location shall pass a final inspection by a Board compliance officer before operations begin.

**F.** A resident full-service or nonprescription drug wholesale permittee shall submit the application packet described under subsection ~~R4-23-605~~(B) for any change of officers in a corporation, excluding the fee and final inspection.

**G.** Distribution restrictions. In addition to the requirements of this subsection, a resident full-service wholesale permittee shall comply with the distribution restrictions specified in A.R.S. § 32-1983.

1. Records.
   a. A full-service drug wholesale permittee shall:
      i. Maintain records to ensure full accountability of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical including dates of receipt and sales, names, addresses, and DEA registration numbers, if required, of suppliers or sources of merchandise, and customer names, addresses, and DEA registration numbers, if required;
      ii. File the records required in subsection ~~(D)~~(G)(1)(a)(i) in a readily retrievable manner for a minimum of ~~two~~ three years; ~~and~~
      iii. Make the records required in subsection ~~(D)~~(G)(1)(a)(i) available upon request during regular business hours for inspection by a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901~~(4)~~(5). Records kept at a central location apart from the business location and not electronically retrievable shall be made available within two business days; and
      iv. In addition to the records requirements of subsection (G)(1)(a)(i), provide a pedigree as specified in A.R.S. § 32-1984(E) for all prescription-only drugs that leave the normal distribution channel as defined in A.R.S. § 32-1981.
   b. A nonprescription drug wholesale permittee shall:
      i. Maintain records to ensure full accountability of any~~,~~ nonprescription drug, precursor chemical, or regulated chemical including dates of receipt and sales, names, addresses, and DEA registration numbers, if required, of suppliers or sources of merchandise, and customer names, addresses, and DEA registration numbers, if required;
      ii. File the records required in subsection ~~(D)~~(G)(1)(b)(i) in a readily retrievable manner for a minimum of ~~two~~ three years; and
      iii. Make the records required in subsection ~~(D)~~(G)(1)(b)(i) available upon request during regular business hours for inspection by a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901~~(4)~~(5). Records kept at a central location apart from the business location and not electronically retrievable shall be made available within two business days.
2. Drug sales.
   a. A full-service drug wholesale permittee shall:
      i. Not sell, distribute, give away, or dispose of, any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical, except in the original container packaged and labeled by the manufacturer or repackager;
      ii. Not package, repackage, label, or relabel any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical;

iii. Not sell, distribute, give away, or dispose of, any narcotic or other controlled substance, or prescription-only drug or device, to anyone except a pharmacy, drug manufacturer, or full-service drug wholesaler currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32;

iv. Not sell, distribute, give away, or dispose of, any nonprescription drug, precursor chemical, or regulated chemical, to anyone except a pharmacy, drug manufacturer, full-service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32;

v. Provide pedigree records upon request, if immediately available, or in no less than two business days from the date of a request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(5);

~~v.~~vi. Maintain a copy of the current permit or license of each person or firm who buys, receives, or disposes of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical; and

~~vi.~~vii. Provide permit and license records upon request, if immediately available, or in no less than two business days from the date of the request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901~~(4)~~(5).

b. A nonprescription drug wholesale permittee shall:

i. Not sell, distribute, give away, or dispose of~~,~~ any nonprescription drug, precursor chemical, or regulated chemical, except in the original container packaged and labeled by the manufacturer or repackager;

ii. Not package, repackage, label, or relabel any nonprescription drug, precursor chemical, or regulated chemical;

iii. Not sell or distribute~~,~~ any nonprescription drug, precursor chemical, or regulated chemical, to anyone except a pharmacy, drug manufacturer, full-service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32;

iv. Maintain a record of the current permit or license of each person or firm who buys, receives, or disposes of any nonprescription drug, precursor chemical, or regulated chemical; and

v. Provide permit and license records upon request, if immediately available, or in no less than two business days from the date of the request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901~~(4)~~(5).

c. Nothing in this subsection shall be construed to prevent the return of a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical to the original source of supply.

3. Out-of-state drug sales.

a. A full-service drug wholesale permittee shall:

i. Not sell, distribute, give away, or dispose of~~,~~ any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical, except in the original container packaged and labeled by the manufacturer or repackager;

ii. Not package, repackage, label, or relabel any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical;

iii. Not sell, distribute, give away, or dispose of~~,~~ any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical, to anyone except a person or firm that is properly permitted, registered, licensed, or certified ~~person or firm of other jurisdictions~~ in another jurisdiction;

iv. Provide pedigree records upon request, if immediately available, or in no less than two business days from the date of the request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(5);

~~iv.~~v. Maintain a copy of the current permit, registration, license, or certificate of each person or firm who buys, receives, or disposes of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical; and

~~v.~~vi. Provide permit, registration, license, and certificate records upon request, if immediately available, or in no less than two business days from the date of the request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901~~(4)~~(5); and

b. A nonprescription drug wholesale permittee shall:

i. Not sell, distribute, give away, or dispose of~~,~~ any nonprescription drug, precursor chemical, or regulated chemical, except in the original container packaged and labeled by the manufacturer or repackager;

ii. Not package, repackage, label, or relabel any nonprescription drug, precursor chemical, or regulated chemical;

iii. Not sell or distribute~~,~~ any nonprescription drug, precursor chemical, or regulated chemical, to anyone except a person or firm that is properly permitted, registered, licensed, or certified ~~person or firm of~~ in another juris-

diction;

iv. Maintain a record of the current permit, registration, license, or certificate of each person or firm who buys, receives, or disposes of any nonprescription drug, precursor chemical, or regulated chemical; and

v. Provide permit, registration, license, or certificate records upon request, if immediately available, or in no less than two business days from the date of the request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901~~(4)~~(5).

4. Cash-and-carry sales.

a. A full-service drug wholesale permittee shall complete a cash-and-carry sale or distribution of~~,~~ any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical, only after:

i. Verifying the validity of the order; ~~and~~

ii. Verifying the identity of the pick-up person~~,~~ for each transaction by confirming that the person or firm represented placed the cash-and-carry order; and

iii. For a prescription-only drug order, verifying that the cash-and-carry sale or distribution is used only to meet the immediate needs of a particular patient of the person or firm who placed the cash-and-carry order; and

b. A nonprescription drug wholesale permittee shall complete a cash-and-carry sale or distribution of~~,~~ any nonprescription drug, precursor chemical, or regulated chemical, only after:

i. Verifying the validity of the order; and

ii. Verifying the identity of the pick-up person~~,~~ for each transaction by confirming that the person or firm represented placed the cash-and-carry order.

**H.** Prescription-only drug returns or exchanges. A full-service drug wholesale permittee shall ensure that any prescription-only drug returned or exchanged by a pharmacy or chain pharmacy warehouse under A.R.S. § 32-1983(A) meets the following criteria:

1. The prescription-only drug is not adulterated or counterfeited, except an adulterated or counterfeited prescription-only drug that is the subject of an FDA or manufacturer recall may be returned for destruction or subsequent return to the manufacturer;
2. The quantity of prescription-only drug returned or exchanged does not exceed the quantity of prescription-only drug that the full-service drug wholesale permittee or a full-service drug wholesale permittee under common ownership sold to the pharmacy or chain pharmacy warehouse; and
3. The pharmacy or chain pharmacy warehouse provides documentation that:
   a. Lists the name, strength, manufacturer, lot number, and expiration date of the prescription-only drug being returned or exchanged; and
   b. States that the prescription-only drug was maintained in compliance with storage conditions prescribed on the drug label or manufacturer's package insert.

**I.** Returned, outdated, damaged, deteriorated, adulterated, misbranded, counterfeited, and contraband drugs.

1. Except as specified in subsection (H)(1) for a prescription-only drug, a full-service drug wholesale permittee shall ensure that the return of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical meets the following criteria.
   a. Any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical that is outdated, damaged, deteriorated, adulterated, misbranded, counterfeited, or contraband or suspected of being adulterated, misbranded, counterfeited, or contraband, or otherwise deemed unfit for human or animal consumption shall be quarantined and physically separated from other narcotics or other controlled substances, prescription-only drugs or devices, nonprescription drugs, precursor chemicals, or regulated chemicals until the narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired as authorized by the Board and the FDA.
   b. Any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical whose immediate or sealed outer or secondary containers or product labeling are misbranded, counterfeited, or contraband or suspected of being misbranded, counterfeited, or contraband shall be quarantined and physically separated from other narcotics or other controlled substances, prescription-only drugs or devices, nonprescription drugs, precursor chemicals, or regulated chemicals until the narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired as authorized by the Board and the FDA. When the immediate or sealed outer or secondary containers or product labeling are determined to be misbranded, counterfeited, or contraband or suspected of being misbranded, counterfeited, or contraband, the full-service drug wholesale permittee shall provide notice of the misbranding, counterfeiting, or contrabandage or suspected misbranding, counterfeiting, or contrabandage within three business days of the determination to the Board, FDA, and manufacturer or wholesale distributor from which the narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or reg-

ulated chemical was acquired.

c. Any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical that has been opened or used, but is not adulterated, misbranded, counterfeited, or contraband or suspected of being misbranded, counterfeited, or contraband, shall be identified as opened or used, or both, and quarantined and physically separated from other narcotics or other controlled substances, prescription-only drugs or devices, nonprescription drugs, precursor chemicals, or regulated chemicals until the narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired as authorized by the Board and the FDA.

d. If the conditions under which a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical has been returned cast doubt on the narcotic's or other controlled substance's, prescription-only drug's or device's, nonprescription drug's, precursor chemical's, or regulated chemical's safety, identity, strength, quality, or purity, the narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical shall be quarantined and physically separated from other narcotics or other controlled substances, prescription-only drugs or devices, nonprescription drugs, precursor chemicals, or regulated chemicals until the narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired as authorized by the Board and the FDA, except as provided in subsection (I)(1)(d)(i).

i. If examination, testing, or other investigation proves that the narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical meets appropriate standards of safety, identity, strength, quality, and purity, it does not have to be destroyed or returned to the manufacturer or wholesale distributor.

ii. In determining whether the conditions under which a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical has been returned cast doubt on the narcotic's or other controlled substance's, prescription-only drug's or device's, nonprescription drug's, precursor chemical's, or regulated chemical's safety, identity, strength, quality, or purity, the full-service drug wholesale permittee shall consider, among other things, the conditions under which the narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical has been held, stored, or shipped before or during its return and the condition of the narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical and the condition of its container, carton, or product labeling as a result of storage or shipping.

e. For any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical identified under subsections (I)(1)(a) or (b), the full-service drug wholesale permittee shall ensure that the identified item or items and other evidence of criminal activity, and accompanying documentation is retained and not destroyed until its disposition is authorized by the Board and the FDA.

2. A nonprescription drug wholesale permittee shall ensure that the return of any nonprescription drug, precursor chemical, or regulated chemical meets the following criteria.

a. Any nonprescription drug, precursor chemical, or regulated chemical that is outdated, damaged, deteriorated, adulterated, misbranded, counterfeited, or contraband or suspected of being adulterated, misbranded, counterfeited, or contraband, or otherwise deemed unfit for human or animal consumption shall be quarantined and physically separated from other nonprescription drugs, precursor chemicals, or regulated chemicals until the nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired as authorized by the Board and the FDA.

b. Any nonprescription drug, precursor chemical, or regulated chemical whose immediate or sealed outer or secondary containers or product labeling are misbranded, counterfeited, or contraband or suspected of being misbranded, counterfeited, or contraband shall be quarantined and physically separated from other nonprescription drugs, precursor chemicals, or regulated chemicals until the nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired as authorized by the Board and the FDA. When the immediate or sealed outer or secondary containers or product labeling are determined to be misbranded, counterfeited, or contraband or suspected of being misbranded, counterfeited, or contraband, the nonprescription drug wholesale permittee shall provide notice of the misbranding, counterfeiting, or contrabandage or suspected misbranding, counterfeiting, or contrabandage within three business days of the determination to the Board, FDA, and manufacturer or wholesale distributor from which the nonprescription drug, precursor chemical, or regulated chemical was acquired.

c. Any nonprescription drug, precursor chemical, or regulated chemical that has been opened or used, but is not adulterated, misbranded, counterfeited, or contraband or suspected of being misbranded, counterfeited, or contraband, shall be identified as opened or used, or both, and quarantined and physically separated from other nonpre-

scription drugs, precursor chemicals, or regulated chemicals until the nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired as authorized by the Board and the FDA.

d. If the conditions under which a nonprescription drug, precursor chemical, or regulated chemical has been returned cast doubt on the nonprescription drug's, precursor chemical's, or regulated chemical's safety, identity, strength, quality, or purity, the nonprescription drug, precursor chemical, or regulated chemical shall be quarantined and physically separated from other nonprescription drugs, precursor chemicals, or regulated chemicals until the nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired as authorized by the Board and the FDA, except as provided in subsection (I)(2)(d)(i).
   i. If examination, testing, or other investigation proves that the nonprescription drug, precursor chemical, or regulated chemical meets appropriate standards of safety, identity, strength, quality, and purity, it does not need to be destroyed or returned to the manufacturer or wholesale distributor.
   ii. In determining whether the conditions under which a nonprescription drug, precursor chemical, or regulated chemical has been returned cast doubt on the nonprescription drug's, precursor chemical's, or regulated chemical's safety, identity, strength, quality, or purity, the nonprescription drug wholesale permittee shall consider, among other things, the conditions under which the nonprescription drug, precursor chemical, or regulated chemical has been held, stored, or shipped before or during its return and the condition of the nonprescription drug, precursor chemical, or regulated chemical and the condition of its container, carton, or product labeling as a result of storage or shipping.

e. For any nonprescription drug, precursor chemical, or regulated chemical identified under subsections (I)(2)(a) or (b), the nonprescription drug wholesale permittee shall ensure that the identified item or items and other evidence of criminal activity, and accompanying documentation is retained and not destroyed until its disposition is authorized by the Board and the FDA.

3. A full-service drug wholesale permittee and nonprescription drug wholesale permittee shall comply with the record-keeping requirements of subsection (G) for all outdated, damaged, deteriorated, adulterated, misbranded, counterfeited and contraband narcotics or other controlled substances, prescription-only drugs or devices, nonprescription drugs, precursor chemicals, or regulated chemicals.

~~H.~~**J.** Facility. A full-service or nonprescription drug wholesale permittee shall:

1. Ensure that the facility occupied by ~~a~~ the full-service or nonprescription drug wholesale permittee is of adequate size and construction, well-lighted inside and outside, adequately ventilated, and kept clean, uncluttered, and sanitary;
2. Ensure that the permittee's warehouse facility:
   a. Is secure from unauthorized entry; and
   b. Has an operational security system designed to provide protection against theft ~~and diversion~~;
3. In a full-service drug wholesale facility, ensure that only authorized personnel may enter areas where any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is kept;
4. In a nonprescription drug wholesale facility, ensure that only authorized personnel may enter areas where any nonprescription drug, precursor chemical, or regulated chemical is kept;
5. In a full-service drug wholesale facility, ensure that any thermolabile narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is stored in an area where room temperature is maintained in compliance with storage conditions prescribed on the product label;
6. In a nonprescription drug wholesale facility, ensure that any thermolabile nonprescription drug, precursor chemical, or regulated chemical is stored in an area where room temperature is maintained in compliance with storage conditions prescribed on the product label;
7. Make the facility available for inspection by a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901~~(4)~~(5) during regular business hours;
8. In a full-service drug wholesale facility, provide a quarantine area for storage of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical that is outdated, damaged, deteriorated, ~~misbranded,~~ adulterated, misbranded, counterfeited, or contraband or suspected of being adulterated, misbranded, counterfeited, or contraband, otherwise deemed unfit for human or animal consumption, or that is in an open container; and
9. In a nonprescription drug wholesale facility, provide a quarantine area for storage of any nonprescription drug, precursor chemical, or regulated chemical that is outdated, damaged, deteriorated, ~~misbranded,~~ adulterated, misbranded, counterfeited, or contraband or suspected of being adulterated, misbranded, counterfeited, or contraband, otherwise deemed unfit for human or animal consumption, or that is in an open container.

~~I.~~**K.** Quality controls.

1. A full-service drug wholesale permittee shall:
   a. Ensure that any ~~fire, flood, or otherwise damaged or deteriorated~~ narcotic or other controlled substance, prescrip-

tion-only drug or device, nonprescription drug, precursor chemical, or regulated chemical that meets the criteria specified in subsection (I)(1) is not sold, distributed, or delivered to any person for human or animal consumption;

b. Ensure that a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is not manufactured, packaged, repackaged, labeled, or relabeled by any of its employees;

c. Ensure that any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical stocked, sold, offered for sale, or delivered is:

i. Kept clean~~;~~,

ii. Protected from contamination and other deteriorating environmental factors~~;~~, and

iii. ~~In compliance~~ Stored in a manner that complies with applicable federal and state law and official compendium storage requirements;

d. Maintain manual or automatic temperature and humidity recording devices or logs to document conditions in areas where any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is stored; and

e. Develop and implement a program to ensure that:

i. Any expiration-dated narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is reviewed regularly;

ii. Any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical~~,~~ that has less than 120 days remaining on the expiration date, or is deteriorated, damaged, or does not comply with federal law, is moved to a quarantine area and not sold or distributed; and

iii. Any quarantined narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to ~~its source of supply~~ the manufacturer or wholesale distributor from which it was acquired.

2. A nonprescription drug wholesale permittee shall:

a. Ensure that any ~~fire, flood, or otherwise damaged or deteriorated~~ nonprescription drug, precursor chemical, or regulated chemical that meets the criteria specified in subsection (I)(2) is not sold, distributed, or delivered to any person for human or animal consumption;

b. Ensure that a nonprescription drug, precursor chemical, or regulated chemical is not manufactured, packaged, repackaged, labeled, or relabeled by any of its employees;

c. Ensure that any nonprescription drug, precursor chemical, or regulated chemical stocked, sold, offered for sale, or delivered is:

i. Kept clean~~;~~,

ii. Protected from contamination and other deteriorating environmental factors~~;~~, and

iii. ~~In compliance~~ Stored in a manner that complies with applicable federal and state law and official compendium storage requirements;

d. Maintain manual or automatic temperature and humidity recording devices or logs to document conditions in areas where any nonprescription drug, precursor chemical, or regulated chemical is stored; and

e. Develop and implement a program to ensure that:

i. Any expiration-dated nonprescription drug, precursor chemical, or regulated chemical is reviewed regularly;

ii. Any nonprescription drug, precursor chemical, or regulated chemical~~,~~ that has less than 120 days remaining on the expiration date, or is deteriorated, damaged, or does not comply with federal law, is moved to a quarantine area and not sold or distributed; and

iii. Any quarantined nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to ~~its source of supply~~ the manufacturer or wholesale distributor from which it was acquired.

**L.** Fingerprint clearance.

1. After receiving the state and federal criminal history record of a designated representative, the Board shall compare the record with the list of criminal offenses that preclude a designated representative from receiving a fingerprint clearance. If the designated representative's criminal history record does not contain any of the offenses listed in subsection (L)(2), the Board shall issue the designated representative a fingerprint clearance.

2. The Board shall not issue a fingerprint clearance to a designated representative who is awaiting trial for or who has been convicted of committing or attempting or conspiring to commit one or more of the following offenses in this state or the same or similar offenses in another state or jurisdiction:

a. Unlawfully administering intoxicating liquors, controlled substances, dangerous drugs, or prescription-only drugs;

b. Sale of peyote;

c. Possession, use, or sale of marijuana, dangerous drugs, prescription-only drugs, or controlled substances;

d. Manufacture or distribution of an imitation controlled substance;

e. Manufacture or distribution of an imitation prescription-only drug;
f. Possession or possession with intent to use an imitation controlled substance;
g. Possession or possession with intent to use an imitation prescription-only drug; or
h. A felony offense involving sale, distribution, or transportation of, offer to sell, transport, or distribute, or conspiracy to sell, transport, or distribute marijuana, dangerous drugs, prescription-only drugs, or controlled substances.

3. If after conducting a state and federal criminal history record check the Board determines that it is not authorized to issue a fingerprint clearance, the Board shall notify the full-service drug wholesale applicant or permittee that employs the designated representative that the Board is not authorized to issue a fingerprint clearance. This notice shall include the criminal history information on which the denial was based. This criminal history information is subject to dissemination restrictions under A.R.S. § 41-1750 and federal law.
4. The issuance of a fingerprint clearance does not entitle a person to employment.

**R4-23-607. Nonresident Permits**

**A.** Permit. A person~~,~~ who is not a resident of Arizona~~,~~ shall not sell or distribute any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical into Arizona without:
1. Possessing a current Board-issued nonresident pharmacy permit, nonresident manufacturer permit, nonresident full-service or nonprescription drug wholesale permit, or nonresident nonprescription drug permit;
2. Possessing a current equivalent license or permit issued by the licensing authority in the jurisdiction where the person or firm resides;
3. ~~Employing~~ For a nonresident pharmacy, employing a pharmacist~~,~~ who is designated as the pharmacist-in-charge~~,~~ and who possesses a current Arizona Board-issued pharmacist license; and
4. For a nonresident pharmacy permit issued before ~~the effective date of subsection (A)(3)~~ April 7, 2007, complying with subsection (A)(3) and submitting to the Board the pharmacist-in-charge's name, current Arizona Board-issued pharmacist license number, and telephone number by November 1, 2007.

**B.** Application. To obtain a nonresident pharmacy, nonresident manufacturer, nonresident full-service or nonprescription drug wholesale, or nonprescription drug permit, a person shall submit a completed application, on a form furnished by the Board, that includes:
1. Business name, address, mailing address, if different, telephone number, and facsimile number;
2. Owner's name, if corporation or partnership, officers or partners, including address and title, and any other trade or business names used;
3. Whether the owner, corporation, or partnership has conducted a similar business in any other jurisdiction and if so, indicate under what name and location;
4. Whether the owner, any officer, or active partner has ever been convicted of an offense involving moral turpitude, a felony offense, or any drug-related offense or has any currently pending felony or drug-related charges, and if so, indicate charge, conviction date, jurisdiction, and location;
5. A copy of the applicant's current equivalent license or permit, issued by the licensing authority in the jurisdiction where the person or firm resides and required by subsection (A)(2);
6. For an application submitted because of ownership change, the former owner's name and business name, if different;
7. Date signed, and applicant's, corporate officer's, partner's, manager's, administrator's, pharmacist-in-charge's, or ~~responsible person's~~ designated representative's verified signature and title~~,~~; and
8. Fee specified in R4-23-205.

**C.** In addition to the requirements of subsection (B), the following information is required on the application:
1. Nonresident pharmacy.
   a. The type of pharmacy;
   b. Whether the owner, any officer, or active partner has ever been denied a pharmacy permit in this state or any other jurisdiction, and if so, indicate where and when;
   c. If applying for a hospital pharmacy permit, the number of beds, manager's or administrator's name, and a copy of the hospital's current equivalent license or permit issued by the licensing authority in the jurisdiction where the person or firm resides;
   d. Pharmacist-in-charge's name, current Arizona Board-issued pharmacist license number, and telephone number; and
   e. For an application submitted because of ownership change, the former pharmacy's name, address, and permit number; and
2. Nonresident manufacturer.
   a. Whether the owner, any officer, or active partner has ever been denied a drug manufacturer permit in this state or any other jurisdiction, and if so, indicate where and when;
   b. A copy of the drug list required by the FDA;
   c. Manager's or responsible person's name, address, and emergency telephone number; and
   d. The firm's current FDA drug manufacturer or repackager registration number and expiration date; and
3. Nonresident full-service drug wholesaler.

a. The designated representative's name, address, and emergency telephone number;
b. Documentation that the designated representative meets the requirements of A.R.S. § 32-1982(B) and the following as specified in A.R.S. § 32-1982(C):
i. A full set of fingerprints from the designated representative; and
ii. The state and federal criminal history record check fee specified by and made payable to the Arizona State Department of Public Safety by money order, certified check, or bank draft; and
c. A $100,000 bond as specified in A.R.S. § 32-1982(D) submitted on a form supplied by the Board; and

~~3.~~4. Nonresident full-service or nonprescription drug wholesaler.
a. The type of drug wholesale permit;
b. Whether the owner, any officer, or active partner has ever been denied a drug wholesale permit in this state or any other jurisdiction, and if so, indicate where and when;
c. The types of drugs, nonprescription, prescription-only, controlled substances, human, or veterinary, the applicant will distribute;
d. Manager's or ~~responsible person's~~ designated representative's name, address, emergency telephone number, and ~~resume~~ resumé indicating educational or experiential qualifications related to drug wholesale operation; and

~~4.~~5. Nonresident nonprescription drug retailer.
a. Whether applying for Category I or Category II permit;
b. Date business started or planned opening date; and
c. Type of business, such as convenience, drug, grocery, or health food store, swap-meet vendor, or vending machine.

**D.** Before issuing a nonresident full-service drug wholesale permit, the Board shall:
1. Receive and approve a completed permit application; and
2. Issue a fingerprint clearance to a qualified designated representative, as specified in R4-23-605(L). If a nonresident full-service drug wholesale permit applicant's designated representative's fingerprint clearance is denied, the nonresident full-service drug wholesale permit applicant shall appoint another designated representative and submit the documentation, fingerprints, and fee required in subsection (C)(3)(b).

**~~D.~~E.** Notification. A permittee shall submit any notification of change required in this subsection as a written notice via mail, fax, or e-mail to the Executive Director within 10 days of the change, except any change of ownership requires that the nonresident permittee comply with subsection (F).
1. Nonresident pharmacy. A nonresident pharmacy permittee shall notify the Board of changes involving the type of pharmacy operated, ownership, address, telephone number, name of business, or pharmacist-in-charge.
2. Nonresident manufacturer. A nonresident manufacturer permittee shall notify the Board of changes involving listed drugs, ownership, address, telephone number, name of business, or manager, including manager's telephone number.
3. Nonresident drug wholesaler. A nonresident full-service or nonprescription drug wholesale permittee shall notify the Board of changes involving the types of drugs sold or distributed, ownership, address, telephone number, name of business, or manager or designated representative, including the manager's or designated representative's telephone number. For a change of designated representative, a nonresident full-service drug wholesale permittee shall submit the documentation, fingerprints, and fee required in subsection (C)(3)(b). If a nonresident full-service drug wholesale permit applicant's designated representative's fingerprint clearance is denied, the nonresident full-service drug wholesale permittee shall appoint another designated representative and submit the documentation, fingerprints, and fee required in subsection (C)(3)(b).
4. Nonresident nonprescription drug retailer. A nonresident nonprescription drug permittee shall notify the Board of changes involving permit category, ownership, address, telephone number, name of business, or manager, including manager's telephone number.

**F.** Change of ownership. Before a change of ownership occurs that involves changes of stock ownership of more than 30% of the voting stock of a corporation or an existing and continuing corporation that is not actively traded on any securities market or over-the-counter market, the prospective owner shall submit the appropriate application packet described under subsections (B) and (C).

**~~E.~~G.** Drug ~~Sales~~ sales.
1. Nonresident pharmacy. A nonresident pharmacy permittee shall:
a. Not sell, distribute, give away, or dispose of~~,~~ any narcotic or other controlled substance or prescription-only drug or device, to anyone in Arizona except:
i. A pharmacy, drug manufacturer, or full-service drug wholesaler currently permitted by the Board;
ii. A medical practitioner currently licensed under A.R.S. Title 32; or
iii. An Arizona resident upon receipt of a valid prescription order for the resident;
b. Not sell, distribute, give away, or dispose of~~,~~ any nonprescription drug, precursor chemical, or regulated chemical, to anyone in Arizona except:
i. A pharmacy, drug manufacturer, full-service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board;

ii. A medical practitioner currently licensed under A.R.S. Title 32; or
iii. An Arizona resident either upon receipt of a valid prescription order for the resident or in the original container packaged and labeled by the manufacturer;

c. Except for a drug sale that results from the receipt and dispensing of a valid prescription order for an Arizona resident, maintain a copy of the current permit or license of each person or firm in Arizona who buys, receives, or disposes of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical; and

d. Provide permit and license records upon request, if immediately available, or in no less than two business days from the date of the request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901~~(4)~~(5).

2. Nonresident manufacturer. A nonresident manufacturer permittee shall:
   a. Not sell, distribute, give away, or dispose of~~,~~ any narcotic or other controlled substance or prescription-only drug or device, to anyone in Arizona except, a pharmacy, drug manufacturer, or full-service drug wholesaler currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32;
   b. Not sell, distribute, give away, or dispose of~~,~~ any nonprescription drug, precursor chemical, or regulated chemical, to anyone in Arizona except, a pharmacy, drug manufacturer, full-service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32;
   c. Maintain a copy of the current permit or license of each person or firm in Arizona who buys, receives, or disposes of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical; and
   d. Provide permit and license records upon request, if immediately available, or in no less than two business days from the date of the request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901~~(4)~~(5).
3. Nonresident full-service drug wholesaler. ~~A~~ In addition to complying with the distributions restrictions specified in A.R.S. § 32-1983, a nonresident full-service drug wholesale permittee shall:
   a. Not sell, distribute, give away, or dispose of~~,~~ any narcotic or other controlled substance or prescription-only drug or device, to anyone in Arizona except a pharmacy, drug manufacturer, or full-service drug wholesaler currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32;
   b. Not sell, distribute, give away, or dispose of~~,~~ any nonprescription drug, precursor chemical, or regulated chemical, to anyone in Arizona except, a pharmacy, drug manufacturer, full-service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32;
   c. Provide pedigree records upon request, if immediately available, or in no less than two business days from the date of the request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(5);
   ~~c.~~d. Maintain a copy of the current permit or license of each person or firm in Arizona who buys, receives, or disposes of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical; and
   ~~d.~~e. Provide permit and license records upon request, if immediately available, or in no less than two business days from the date of the request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901~~(4)~~(5).
4. Nonresident nonprescription drug wholesaler. A nonresident nonprescription drug wholesale permittee shall:
   a. Not sell, distribute, give away, or dispose of~~,~~ any nonprescription drug, precursor chemical, or regulated chemical, to anyone in Arizona except, a pharmacy, drug manufacturer, full-service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32;
   b. Maintain a copy of the current permit or license of each person or firm in Arizona who buys, receives, or disposes of any nonprescription drug, precursor chemical, or regulated chemical; and
   c. Provide permit and license records upon request, if immediately available, or in no less than two business days from the date of the request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901~~(4)~~(5).
5. Nonresident nonprescription drug retailer. A nonresident nonprescription drug permittee shall not:
   a. Sell, distribute, give away, or dispose of~~,~~ a nonprescription drug, precursor chemical, or regulated chemical to anyone in Arizona except in the original container packaged and labeled by the manufacturer;
   b. Package, repackage, label, or relabel any drug, precursor chemical, or regulated chemical; or
   c. Sell, distribute, give away, or dispose of~~,~~ any drug, precursor chemical, or regulated chemical to anyone in Arizona that exceeds its expiration date, is contaminated or deteriorated from excessive heat, cold, sunlight, moisture, or other factors, or does not comply with federal law.

~~F.~~ **H.** When selling or distributing any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical into Arizona, a nonresident pharmacy, nonresident manufacturer, nonresident full-service or nonprescription drug wholesale, or nonprescription drug permittee shall comply with federal law, the permittee's resident state drug law, and this Section.

# NOTICE OF FINAL RULEMAKING

## TITLE 9. HEALTH SERVICES

## CHAPTER 5. DEPARTMENT OF HEALTH SERVICES
## CHILD CARE FACILITITES

[R07-348]

## PREAMBLE

**1. Sections Affected** | **Rulemaking Action**

| | |
|---|---|
| R9-5-101 | Amend |
| R9-5-301 | Amend |
| R9-5-303 | Amend |
| R9-5-310 | New Section |

**2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):**

Authorizing statutes: A.R.S. §§ 36-104(3) and 36-136(F)

Implementing statutes: A.R.S. § 36-898

**3. The effective date of the rules:**

December 1, 2007

**4. A list of all previous notices appearing in the *Register* addressing the final rules:**

Notice of Rulemaking Docket Opening: 12 A.A.R. 4105, November 3, 2006

Notice of Rulemaking Docket Opening: 13 A.A.R. 1988, June 8, 2007

Notice of Proposed Rulemaking: 13 A.A.R. 1964, June 8, 2007

**5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:**

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Division of Licensing Services
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or

Name: Kathleen Phillips, Rules Administrator

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**6. An explanation of the rules, including the agency's reasons for initiating the rules:**

Laws 2006, Ch. 390, § 2 created A.R.S. § 36-898, which requires the Arizona Department of Health Services (Department) to adopt a policy to provide parents, guardians, children, and personnel with at least 48-hours' notice before pesticides are applied to a licensed child care facility. The Department is amending the Child Care Facilities licensing rules to include a policy that is consistent with A.R.S. § 36-898.

The Department is deleting unnecessary and obsolete provisions and reorganizing the Child Care Facilities licensing rules to make the rules more clear, concise, and understandable to the reader.

Changes will conform to rulemaking format and style requirements of the Governor's Regulatory Review Council and the Office of the Secretary of State.

**7. A reference to any study relevant to the rules that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rules, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:**

The Department did not review or rely on any study related to this rulemaking.

**8. A showing of good cause why the rules are necessary to promote a statewide interest if the rules will diminish a previous grant of authority of a political subdivision of this state:**

Not applicable

**9. The summary of the economic, small business, and consumer impact:**

The rules for Child Care Facilities apply to the approximately 2,210 child care facilities currently licensed by the Department.

In this economic impact summary, "minimal" means less than $1,000; "moderate" means $1,000 to $10,000; "substantial" means greater than $10,000; and "significant" means meaningful or important, but not readily subject to quantification.

**Cost Bearers**

- The Department will incur a minimal cost from the rulemaking process, a minimal-to-moderate cost in notifying licensees of the changes to the rules, and a significant cost for inspecting facilities for the additional rule requirements.
- A licensee will incur a minimal cost implementing the new rules and a minimal cost for posting the notification of pesticide application.
- A parent may incur a minimal cost if a licensee passes on the cost to implement the rules to the parent.

**Beneficiaries**

- A child, a parent, or an employee that may be affected by a pesticide application. The notice allows a child, a parent, or an employee to make alternative arrangements to prevent from being affected by the pesticide application.

The Department does not believe that any other persons will be impacted by the changes in this rulemaking.

The Department has determined that the benefits outweigh the costs associated with this rulemaking.

**10. A description of the changes between the proposed rules, including supplemental notices, and final rules, (if applicable):**

In R9-5-101(70) the term "pesticide" was removed from the definition of "material safety data sheet."

In R9-5-301(F) the phrase "not registered with the Department, as prescribed by A.R.S. § 36-883.02" was replaced with the phrase "that is not a staff member."

Minor technical and grammatical changes were made by the Department to improve clarity, conciseness, and understandability.

**11. A summary of the comments made regarding the rules and the agency response to them:**

Although the Department held an oral proceeding, the Department did not receive any oral or written comments on the proposed rules

**12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:**

Not applicable

**13. Incorporations by reference and their location in the rules:**

Not applicable

**14. Were these rules previously made as emergency rules?**

No

**15. The full text of the rules follows:**

**TITLE 9. HEALTH SERVICES**

**CHAPTER 5. DEPARTMENT OF HEALTH SERVICES**
**CHILD CARE FACILITIES**

**ARTICLE 1. GENERAL**

Section
R9-5-101. Definitions

**ARTICLE 3. FACILITY ADMINISTRATION**

Section
R9-5-301. General Licensee Responsibilities
R9-5-303. Posting of Notices
R9-5-310. Pesticides

**ARTICLE 1. GENERAL**

**R9-5-101. Definitions**
No change
1. No change
2. No change
   a. No change
   b. No change
   c. No change
3. No change
4. No change
   a. No change
   b. No change
   c. No change
   d. No change
   e. No change
   f. No change
5. No change
6. No change
7. No change
8. No change
9. No change
10. No change
11. No change
    a. No change
    b. No change
12. No change
13. No change
14. No change
15. No change
16. No change
17. No change
18. No change
19. No change
20. No change
21. No change
22. No change
23. No change
24. No change
    a. No change
    b. No change
    c. No change
    d. No change

i. No change
ii. No change
iii. No change
iv. No change
v. No change
25. No change
26. No change
27. No change
    a. No change
    b. No change
    c. No change
28. No change
29. No change
30. No change
31. No change
32. No change
    a. No change
    b. No change
    c. No change
    d. No change
33. No change
34. No change
35. No change
36. No change
37. No change
38. No change
    a. No change
    b. No change
    c. No change
    d. No change
39. No change
40. No change
41. No change
42. No change
43. No change
44. No change
45. No change
46. No change
47. No change
    a. No change
    b. No change
48. No change
    a. No change
    b. No change
49. No change
50. No change
51. No change
52. No change
53. No change
54. No change
55. No change
56. No change
    a. No change
    b. No change
    c. No change
57. No change
58. No change
59. No change
    a. No change

b. No change
60. No change
61. No change
62. No change
a. No change
b. No change
c. No change
63. No change
64. No change
65. "Licensed applicator" has the same meaning as in A.R.S. § 32-2301.
~~65.~~66. No change
~~66.~~67. No change
~~67.~~68. No change
~~68.~~69. No change
70. "Material safety data sheet" means the information provided by a manufacturer describing chemical qualities, hazards, safety precautions, and emergency procedures to be followed in case of a spill, fire, or other emergency.
~~69.~~71. No change
~~70.~~72. No change
a. No change
b. No change
~~71.~~73. No change
~~72.~~74. No change
~~73.~~75. No change
~~74.~~76. No change
~~75.~~77. No change
~~76.~~78. No change
a. No change
b. No change
~~77.~~79. No change
~~78.~~80. No change
~~79.~~81. No change
a. No change
b. No change
c. No change
~~80.~~82. No change
~~81.~~83. No change
~~82.~~84. No change
a. No change
b. No change
~~83.~~85. No change
86. "Pesticide" has the same meaning as in A.R.S. § 32-2301.
87. "Pesticide label" means the written, printed, or graphic matter approved by the United States Environmental Protection Agency on, or attached to, a pesticide container.
~~84.~~88. No change
~~85.~~89. No change
a. No change
b. No change
c. No change
d. No change
e. No change
~~86.~~90. No change
a. No change
b. No change
~~87.~~91. No change
~~88.~~92. No change

~~89.~~93. No change
~~90.~~94. No change-
~~91.~~95. No change
~~92.~~96. No change

~~93.~~97. No change
~~94.~~98. No change
a. No change
i. No change
ii. No change
iii. No change
b. No change
~~95.~~99. No change
~~96.~~100. No change
a. No change
b. No change
~~97.~~101. No change
~~98.~~102. No change
a. No change
i. No change
ii. No change
b. No change
i. No change
ii. No change
iii. No change
iv. No change
~~99.~~103. No change
~~100.~~104. No change
~~101.~~105. No change
~~102.~~106. No change
~~103.~~107. No change
a. No change
b. No change
c. No change
d. No change
e. No change
f. No change
~~104.~~108. No change
~~105.~~109. No change
~~106.~~110. No change
~~107.~~111. No change
~~108.~~112. No change
~~109.~~113. No change
~~110.~~114. No change
a. No change
b. No change
~~111.~~115. No change
~~112.~~116. No change
~~113.~~117. No change
~~114.~~118. No change

## ARTICLE 3. FACILITY ADMINISTRATION

**R9-5-301. General Licensee Responsibilities**

**A.** ~~A licensee is responsible for the compliance of a facility with A.R.S. § 36-881 et seq. and these rules. The~~ A licensee shall designate a facility director who acts on behalf of the licensee and is responsible for the daily ~~on-site~~ onsite operation of a facility.

**B.** A licensee shall ensure that ~~a facility director~~:

1. A facility director ~~Designates~~ designates in writing, an individual to act on behalf of the facility director when the facility director is not present in the facility ~~and that~~;
2. ~~the~~ The individual designated in subsection (B)(1):
   a. ~~has~~ Has access to all records necessary for performance of the facility director's duties~~.~~,
   ~~a.~~b. ~~The individual shall be~~ Is 21 years of age or older, and ~~provide~~
   c. Provides documentation of any of the following:
      i. High school or high school equivalency diploma and six credit hours or more in early childhood, child

development, or closely related field ~~in~~ from an accredited college or university, or 30 actual hours of instruction, provided in conferences, seminars, lectures, or workshops in the areas of early childhood, child development, or closely related field, and 12 months or more of child care experience;

ii. N.A.C., C.D.A., C.C.P., or C.P.C. credential and at least 12 months of child care experience;

iii. A minimum of 24 credit hours from an accredited college or university, including at least six credit hours of course work in the areas of early childhood, child development, or closely related field, and 12 months of child care experience;

iv. Associate degree from an accredited college or university in the areas of early childhood, child development, or closely related field, and six months of child care experience; or

v. Bachelor degree from an accredited college or university in the areas of early childhood, child development, or closely related field, and 3 months of child care experience.

~~b. A licensee has 12 months from the effective date of these rules to comply with this requirement.~~

~~2.~~3. ~~Supervises~~ A facility director supervises or assigns a teacher-caregiver to supervise each staff member that does not meet the qualifications of R9-5-401(2) and each student-aide~~;~~, and

~~3.~~4. ~~Prepares~~ A facility director prepares a dated attendance record for each day and ensures that each staff member records on the attendance record the time of each arrival and departure of the staff member.

**~~B.~~C.** A licensee shall develop and implement written facility policies and procedures required for the daily ~~on-site~~ onsite operation of the facility as prescribed in A.R.S. § 36-881 et seq. and these rules.

**~~C.~~D.** A licensee shall ~~ensure that parents are informed that they have~~ notify a parent of the following:

1. That the parent:
   a. Has access to all areas of a facility where child care services are provided during hours of operation, and ~~that parents are~~
   b. Is permitted to participate in any child care activity~~.~~ that the parent's child is participating in; and
2. Of the procedures for notifying a parent at least 48 hours before a pesticide is applied on a facility's premises.

**~~D.~~E.** A licensee shall ensure that the following individuals are allowed immediate access to facility premises during hours of operation:

1. A parent or an individual designated in writing by the parent; or
2. A representative of:
   a. The Department,
   b. Local health department,
   c. Child Protective Services, or
   d. Local fire department or State Fire Marshal.

**~~E.~~F.** A licensee shall, with the exception of individuals listed in subsection ~~(D)~~ (E), ensure that a staff member accompany and monitor any individual ~~not registered with the Department, as prescribed by A.R.S. § 36-883.02~~ that is not a staff member, who is on facility premises to provide repair, maintenance, supplemental education, or other services where children are present.

**~~F.~~G.** A licensee shall ensure that each staff member and individual who is a resident at the facility submits one of the following documents provided by a health care provider as evidence of current freedom from pulmonary tuberculosis:

1. A report of a negative Mantoux skin test administered to a resident at the facility or to a staff member no later than 12 hours after the starting date of employment; or
2. A physician's written statement that the staff member or the individual who is a resident in the facility is currently free from tuberculosis.

**~~G.~~H.** If an enrolled child has an accident, injury, or emergency that requires medical treatment by a health care provider while attending a facility, the licensee shall ensure that a staff member:

1. Notifies the child's parent immediately after the accident, injury, or emergency;
2. Documents the date, time, and location of the child's accident, injury, or emergency, the method used to notify the parent, and the time the parent was notified; and
3. Maintains documentation of the accident, injury, or emergency on facility premises in a file that is separate from the current Emergency, Information, and Immunization card for 24 months from the date of the child's disenrollment.

**~~H.~~I.** A licensee shall ensure that at least one staff member who has current training in first aid and at least one staff member who has current training in CPR, as required by R9-5-403(E), is present at all times on facility premises, on field trips or while transporting enrolled children in a facility's motor vehicle or a vehicle designated by the licensee to transport children. This requirement may be met by a single staff member who has current training in both first aid and CPR.

**~~I.~~J.** A licensee shall prohibit the use or possession of the following items when an enrolled child is on facility premises, during hours of operation, or in any motor vehicle when used by the licensee for transportation of enrolled children:

1. Any beverage containing alcohol;
2. A controlled substance as listed in A.R.S. Title 36, Chapter 27, Article 2;
3. A dangerous drug as ~~listed~~ defined in A.R.S. § 13-3401~~(6)~~;
4. A prescription medication as defined in A.R.S. § 32-1901~~(63)~~ except where used in the manner prescribed; or

5. A firearm as defined ~~by~~ in A.R.S. § 13-105~~(17)~~.

**~~J.~~K.** At least once ~~every 30 days~~ a month, and at different times of the day, a licensee shall ensure that an unannounced fire evacuation drill is conducted that includes each staff member and child at the facility.
1. If child care services for a child with special needs are provided at a facility, the licensee shall provide for the child's participation in each fire evacuation drill in accordance with the child's individualized plan as specified in R9-5-507(A)(1).
2. A licensee shall keep a written record of each fire evacuation drill on facility premises for 12 months from the date of the drill.

**~~K.~~L.** A licensee shall ensure that a written performance evaluation of each staff member is conducted every 12 months from the date of employment.

**R9-5-303. Posting of Notices**

**A.** A licensee shall designate a wall area or notice board inside the facility's entrance, in a place that can be conspicuously viewed by individuals entering or leaving the facility, for the posting of the:
1. Current license;
2. Name of the facility director;
3. Name of the individual designated ~~as prescribed by R9-5-301(A)(1)~~ to act on behalf of the facility director when the facility director is not present in the facility, as prescribed by R9-5-301(B)(1);
4. Schedule of child care services fees and policy for the refund of fees as prescribed by A.R.S. § 36-882(K);
5. Breakfast, lunch, dinner, and snack menus for each calendar week at the beginning of the calendar week;
6. Notice of the presence of any communicable disease or infestation ~~described in R9-6-202(C)~~ listed in 9 A.A.C. 6, Article 2, Table 2, from the date of discovery through the incubation period of the communicable disease or infestation;
7. Notice of denial, revocation, or suspension as prescribed by A.R.S. § 36-888;
8. Notice of an intermediate sanction imposed as prescribed by A.R.S. § 36-891.01;
9. Notice of legal injunction imposed as prescribed by A.R.S. § 36-886.01; and
10. Notice of the availability of facility inspection reports for public viewing.

**B.** A licensee shall ensure that the licensed capacity of each activity area or room is posted in that activity area ~~or room~~.

**C.** A licensee shall post a notification of pesticide application in each activity area and in each entrance of a facility, at least 48 hours before a pesticide is applied on the facility's premises, containing:
1. The date and time of the pesticide application, and.
2. A statement that written pesticide information is available from the licensee upon request.

**D.** A licensee is exempt from the provisions in subsection (C), as prescribed by A.R.S. § 36-898(C).

**R9-5-310. Pesticides**

**A.** A licensee shall make written pesticide information available to a parent, upon a parent's request, at least 48 hours before a pesticide application occurs on a facility's premises, containing:
1. The brand name, concentration, rate of application, and any use restrictions required by the label of the herbicide or specific pesticide;
2. The date and time of the pesticide application;
3. The pesticide label and the material safety data sheet; and
4. The name and telephone number of the pesticide business licensee and the name of the licensed applicator.

**B.** A licensee is exempt from the provisions in subsection (A), as prescribed by A.R.S. § 36-898(C).

# NOTICE OF FINAL RULEMAKING

## TITLE 17. TRANSPORTATION

## CHAPTER 5. DEPARTMENT OF TRANSPORTATION COMMERCIAL PROGRAMS

[R07-347]

## PREAMBLE

| 1. Sections Affected | Rulemaking Action |
|---|---|
| Article 6 | Amend |
| R17-5-601 | Amend |
| R17-5-602 | Renumber |

| | |
|---|---|
| R17-5-602 | New Section |
| R17-5-603 | Renumber |
| R17-5-603 | New Section |
| R17-5-604 | Renumber |
| R17-5-604 | Amend |
| R17-5-605 | Renumber |
| R17-5-605 | New Section |
| R17-5-606 | Renumber |
| R17-5-606 | Amend |
| R17-5-607 | Renumber |
| Appendix A | Renumber |
| Appendix B | Renumber |
| Appendix C | Renumber |
| R17-5-607 | Amend |
| R17-5-608 | Renumber |
| R17-5-608 | Amend |
| R17-5-609 | Renumber |
| R17-5-609 | Amend |
| R17-5-610 | Renumber |
| Exhibit A | Renumber |
| Exhibit B | Renumber |
| Appendix A | Renumber |
| Appendix B | Renumber |
| Appendix C | Renumber |
| R17-5-610 | Amend |
| Appendix A | Repeal |
| Appendix B | Repeal |
| Appendix C | Repeal |
| R17-5-611 | Renumber |
| R17-5-611 | Amend |
| R17-5-612 | Renumber |
| R17-5-612 | Amend |
| R17-5-613 | New Section |
| Article 7 | New Article |
| R17-5-701 | New Section |
| R17-5-702 | New Section |
| R17-5-703 | Renumber |
| Exhibit A | Renumber |
| Exhibit B | Renumber |
| R17-5-703 | Amend |
| Exhibit A | Repeal |
| Exhibit B | Repeal |
| R17-5-704 | New Section |
| R17-5-705 | New Section |
| R17-5-706 | New Section |
| R17-5-707 | New Section |
| R17-5-708 | New Section |

**2. The statutory authority for the rulemaking, including both the authorizing statutes (general) and the statutes the rules are implementing (specific):**

Authorizing statutes: A.R.S. §§ 28-366, 28-1462 and 28-1465

Implementing statutes: A.R.S. §§ 28-1301, 28-1462 through 28-1467, 41-1009, 41-1073, 41-1076, 41-1079, and A.R.S. Title 41, Chapter 6, Article 6

**3. The effective date of the rules:**

December 1, 2007

**4. A list of all previous notices appearing in the *Register* addressing the final rules:**

Notice of Rulemaking Docket Opening: 12 A.A.R. 3245, September 8, 2006

Notice of Proposed Rulemaking: 13 A.A.R. 1594, May 11, 2007

Notice of Oral Proceeding on Proposed Rulemaking: 13 A.A.R. 2178, June 22, 2007

**5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:**

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E-mail: jlindley@azdot.gov

Please visit the ADOT web site to track progress of these rules and any other agency rulemaking matters at www.azdot.gov/mvd/mvdrules/rules.asp.

**6. An explanation of the rules, including the agency's reasons for initiating the rulemaking:**

The Arizona Department of Transportation, Motor Vehicle Division, is amending existing rules, and creating additional rules, to incorporate recent legislative changes provided under Laws 2006, Ch. 271, §§ 3 and 6. The new laws modify the definitions of ignition interlock device manufacturer and installer, and require that the manufacturers and installers receive Division certification before installing or offering an ignition interlock device for installation under Arizona law. The rules provide for the administration, enforcement, certification, and de-certification of ignition interlock device manufacturers and installers. Additionally, minor changes were made to update related citations, provide modernization in the rule drafting style, and to improve the clarity, conciseness, and understandability of the rules.

**7. A reference to any study relevant to the rules that the agency relied on in its evaluation of or justification for the rules, where the public may obtain or review each study, all data underlying each study, and any analysis of the study and other supporting material:**

None

**8. A showing of good cause why the rules are necessary to promote a statewide interest if the rules will diminish a previous grant of authority of a political subdivision of this state:**

Not applicable

**9. The summary of the economic, small business, and consumer impact:**

This rulemaking adds a new requirement for ignition interlock device manufacturers to ensure adequate and consistent levels of training for its authorized installers. Additionally, the rules incorporate many of the best practice guidelines developed by the ignition interlock industry, which some of the affected device manufacturers are currently using while conducting business in other states. The Division anticipates these rules will have only a minimal economic impact on device manufacturers as they are currently required by rule to provide a certain degree of oversight regarding the certified ignition interlock device related activities of their authorized installers. Additional administrative costs may result from the initial programming and implementation of the updated electronic reporting requirements. However, the Division anticipates these costs will be minimal to both the ignition interlock device manufacturers and their installers.

By streamlining most certified ignition interlock device reporting into one electronic reporting process, and eliminating most of the old cumbersome paper reporting processes, the Division anticipates that all ignition interlock device manufacturers and installers will experience a benefit of substantial savings. The updated electronic reporting system will expedite the recording of all certified ignition interlock device related information needed for the Division and law enforcement personnel to promptly verify a participant's compliance with the program. Program participants benefit significantly by the immediate recording and updating of their compliance information on file with the Division.

**10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):**

The Division removed outdated language under R17-5-611(A), which originally provided specific mileage criteria for authorized installers to use in determining the appropriate response time for providing emergency assistance to participants. The Division and industry representatives agree that the language is no longer necessary since the authorized installers can now provide immediate device related troubleshooting information to the participant over the phone. However, the Division shall require that a service representative respond to the participant telephonically within two hours after receiving an emergency call and the certified ignition interlock device shall be repaired or replaced within 48 hours.

At the request of an industry representative, the Division modified the existing monthly reporting requirement under R17-5-612, which will now allow authorized installers to report certain information to the Division on a quarterly basis. Additionally, under R17-5-706, the authorized installer's requirement to notify the Division within 72 hours of discovering a failed device has been removed as non-applicable since the installer would have already provided the Division with immediate electronic notification under R17-5-610.

In addition to some minor grammatical and formatting changes made at the request of G.R.R.C. staff, the Division removed language initially proposed under R17-5-602 and R17-5-606, as well as some existing language under R17-5-607, that as initially proposed would have rendered manufacturers and installers ineligible to reapply for Division-

certification after a cancellation. These corrections provide clarification that a cancellation does not prohibit a manufacturer or installer from submitting a subsequent application for certification if all certification requirements are met, as indicated under R17-5-607 and R17-5-707.

**11. A summary of the comments made regarding the rules and the agency response to them:**

A member of the regulated community asked the Division to further clarify whether or not a participant's second refusal to perform a requested rolling retest results in the recording of a second circumvention violation. The Division responded that for the purpose of extending the duration of a participant's certified ignition interlock device requirement under A.R.S. § 28-1464(K), a second circumvention violation is applicable only if the participant refuses to perform the requested rolling retest in a separate incident.

**12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:**

None

**13. Incorporations by reference and their location in the rules:**

None

**14. Were these rules previously made as emergency rules?**

No

**15. The full text of the rules follows:**

## TITLE 17. TRANSPORTATION

## CHAPTER 5. DEPARTMENT OF TRANSPORTATION COMMERCIAL PROGRAMS

### ARTICLE 6. IGNITION INTERLOCK ~~DEVICES~~ DEVICE MANUFACTURERS

Section
R17-5-601. ~~Ignition Interlock Device Program~~ Definitions
R17-5-602. Ignition Interlock Device Manufacturer Certification; Expiration
R17-5-603. Device Requirements, Technical Specifications, and Standards for Setup and Calibration
~~R17-5-602.~~R17-5-604. Ignition Interlock Device Certification; Application Requirements
R17-5-605. Application Processing; Time-frames; Exception
~~R17-5-603.~~R17-5-606. Application Completeness; ~~Refusal to Certify an~~ Denial of Ignition Interlock Device Certification; Hearing~~.~~
~~R17-5-604.~~R17-5-607. Cancellation of Certification; Hearing
~~R17-5-605.~~R17-5-608. Modification of a Certified Ignition Interlock Device Model
~~R17-5-606.~~R17-5-609. Manufacturer Referral to ~~Authorized~~ Division-certified Installers; Manufacturer Oversight of its Authorized Installers
~~R17-5-607.~~R17-5-610. Installation Verification; Accuracy Check; Noncompliance ~~Report~~ and Removal Reporting
Appendix A. ~~Ignition Interlock Installation Verification~~ Repealed
Appendix B. ~~Ignition Interlock Accuracy Check~~ Repealed
Appendix C. ~~Ignition Interlock Noncompliance Report~~ Repealed
~~R17-5-608.~~R17-5-611. Emergency Assistance by Manufacturers and Authorized Installers; Continuity of Service to Participants
~~R17-5-609.~~R17-5-612. Records Retention; Submission of Copies and ~~Monthly~~ Quarterly Reports; Periodic ~~Audits~~ Inspections
R17-5-613. Ignition Interlock Investigator

### ARTICLE 7. ~~REPEALED~~ IGNITION INTERLOCK DEVICE INSTALLERS

Section
R17-5-701. ~~Repealed~~ Definitions
R17-5-702. ~~Repealed~~ Ignition Interlock Device Installer Certification; Application Requirements
~~R17-5-703.~~ ~~Repealed~~
~~R17-5-610.~~R17-5-703. Ignition Interlock Device Installer Bond Requirements
Exhibit A. ~~Ignition Interlock Installer Bond~~ Repealed
Exhibit B. ~~Ignition Interlock Installer Bond~~ Repealed
R17-5-704. ~~Repealed~~ Division-certified Installer Responsibilities
R17-5-705. ~~Repealed~~ Installer-certified Service Representatives
R17-5-706. ~~Repealed~~ Accuracy and Compliance Check; Requirements

## ARTICLE 6. IGNITION INTERLOCK ~~DEVICES~~ DEVICE MANUFACTURERS

**R17-5-601. ~~Ignition Interlock Device Program~~ Definitions**

In ~~Sections R17-5-602 through R17-5-610~~ addition to the definitions under A.R.S. § 28-1301, in this Article and A.A.C. R17-4-408, unless the context otherwise requires:

"Alcohol" means ethyl alcohol, also called ethanol.

"Alcohol concentration" means the weight amount of alcohol contained in a unit volume of breath or air, measured in grams of ethanol/210 liters of breath or air and expressed as grams/210 liters.

"Alveolar breath sample" means the last portion of a prolonged, uninterrupted exhalation from which breath alcohol concentrations can be determined.

"Anticircumvention feature" means any feature or circuitry incorporated into the ignition interlock device that is designed to prevent human activity that would cause the device not to operate as intended.

~~"Audit" means an examination by Arizona Department of Transportation, Motor Vehicle Division personnel of participant records, and supplies of warning labels and written instructions.~~

"Authorized installer" means a person or entity appointed by a manufacturer, and certified by the Division, to install and service a certified ignition interlock ~~devices~~ device model provided by the manufacturer.

"Breath alcohol test" means analysis of a sample of the person's expired alveolar breath to determine alcohol concentration.

"Calibration" means the testing, adjustment, or systematic standardization of an ignition interlock device to determine and verify ~~the device's~~ its accuracy.

"Cancellation" means the withdrawal of a certification granted by the Division under this Article, which prohibits a previously certified ignition interlock device manufacturer, its authorized installer, or the authorized installer's service center from offering, installing, or servicing an ignition interlock device under Arizona law.

"Certification" means a status granted by the Division under this Article, which permits a certified ignition interlock device manufacturer, an authorized installer, or an authorized installer's service center to offer, install, or service an ignition interlock device under Arizona law.

~~"Certified ignition interlock device" has the meaning prescribed in A.R.S. § 28-1301(1).~~

"Customer number" means the system-generated, or other distinguishing number, assigned by the Division to each person conducting business with the Division. The customer number of a private individual is generally the person's driver license or non-operating identification license number.

~~"Data logger sheet" means a printed report generated from an ignition interlock device that contains all activities, data recordings, and actions pertaining to the device.~~

"Data storage system" means a computerized recording of all events monitored by an installed ignition interlock device, which may be reproduced in the form of specific reports.

"Director" means the Assistant Director for the Motor Vehicle Division of the Arizona Department of Transportation or the Assistant Director's designee.

"Division" means the Arizona Department of ~~Transportation,~~ Transportation's Motor Vehicle Division.

"Emergency bypass" means an event that permits a vehicle equipped with an ignition interlock device to be started without requiring successful completion of a required breath alcohol test.

"Emergency situation" means a circumstance where the participant declares to a Division-certified installer that the vehicle needs to be moved as a condition of law or the participant has a valid and urgent need to operate the vehicle.

"False sample" means any sample other than the unaltered, undiluted, or unfiltered alveolar breath sample coming from the participant.

"Filtered breath sample" means any mechanism by which there is an attempt to remove alcohol from the human breath sample.

"Fixed-site service center" means a permanent location operated by an installer for conducting business and providing services related to a certified ignition interlock device.

"Free restart" means a function of a certified ignition interlock device that will allow a participant to restart the vehicle, under the conditions provided in R17-5-603, without having to complete another breath alcohol test.

~~"Ignition interlock device" has the meaning prescribed in A.R.S. § 28-1301(4).~~

"Ignition interlock investigator" means a Division representative authorized under R17-5-613 to inspect and monitor

ignition interlock device manufacturers, installers, and service centers for continuous compliance with Articles 6 and 7 of this Chapter and A.R.S. Title 28, Chapter 4, Article 5.

"Illegal start" means the starting of a vehicle equipped with an ignition interlock device without successfully completing the required breath alcohol test.

"Independent laboratory" means a testing facility, not owned or operated by a manufacturer, that can test an ignition interlock device according to Sections 1 and 2 of the National Highway Traffic Safety Administration (NHTSA) Specifications for Breath Alcohol Ignition Interlock Devices (BAIIDs), 57 FR 11772 to 11787, April 7, 1992.

"Installer" means a manufacturer, a manufacturer's authorized representative, or a person or entity responsible for the day-to-day operations of a service center, who is certified by the Division to install a certified ignition interlock device and to provide certified ignition interlock device related services to the public.

"Installer-certified service representative" means any individual who has successfully completed all requirements under R17-5-705, and has received certification from an installer to install, inspect, download, calibrate, repair, monitor, maintain, service, or remove a specific certified ignition interlock device.

"Interlock" means the mechanism which prevents a motor vehicle from starting when the breath alcohol concentration of a participant meets or exceeds a preset value.

"Lock-out condition" means the operational status of a certified ignition interlock device, which after recording any violation of A.R.S. Title 28, Chapter 4, Article 5, immobilizes a participant's vehicle by disallowing further operation of the device. The lock-out feature is built into an ignition interlock device through manufacturer software or firmware, and once activated, the device must be re-set by the manufacturer's authorized installer.

"Manufacturer" means a person or entity that ~~provides ignition interlock devices, requests the Division to certify a model of ignition interlock device, and appoints and oversees authorized installers of the certified ignition interlock device~~ produces a certified ignition interlock device and is certified by the Division to offer the device for installation under Arizona law.

"Manufacturer's representative" means an individual or entity designated by a manufacturer to represent or act on behalf of the manufacturer of a certified ignition interlock device.

"Material modification" means a change to a certified ignition interlock device that affects the ~~functioning~~ functionality of the device.

"Mobile service center" means the portable operation of an installer, whether contained within a vehicle or temporarily erected on location, which includes all personnel and equipment necessary for an installer to conduct ignition interlock device related business and services, separately and simultaneously, with its parent fixed-site service center.

"Negative result" means a test result indicating that the alcohol concentration is less than the startup set point value.

"NHTSA" means the United States Department of Transportation's National Highway Traffic Safety Administration.

"NHTSA specifications" means the specifications for breath alcohol ignition interlock devices published at 57 FR 11772 to 11787, April 7, 1992.

"Participant" means a person who is ordered by an Arizona court or the Division to equip each motor vehicle operated by the person with a functioning certified ignition interlock device and who becomes an authorized installer's customer for installation and servicing of the certified ignition interlock device.

"Positive result" means a test result indicating that the alcohol concentration meets or exceeds the startup set point value.

"Purge" means any mechanism which cleanses or removes a previous breath or reference sample from the device and specifically removes alcohol.

"Reference sample device" means a device containing a sample of known alcohol concentration.

"Retest set point" has the same meaning as startup set point.

"Rolling retest" means an additional breath alcohol test required of the participant at random intervals. This test is in addition to the initial test required to start the vehicle.

"Service center" means a certified ignition interlock device service center operated by an installer who meets and maintains all certification and inspection requirements of the Division under R17-5-707, whether operated on a fixed-site or mobile.

"Startup set point" means the alcohol concentration value, established by the Division under R17-5-603, which is determined by the Division to be the point at which, or above, an ignition interlock device shall disable the ignition of a motor vehicle.

~~"Use" means to install, operate, service, repair, or remove an ignition interlock device.~~

"Violation" means any of several events including, but not limited to, high alcohol concentrations, illegal starts, and

failures to perform rolling retests.

"Violation reset" means the unplanned servicing of a certified ignition interlock device and the downloading of information from its data storage system by a service center when required as a result of an over-accumulation of violations.

**R17-5-602. Ignition Interlock Device Manufacturer Certification; Expiration**

**A.** An ignition interlock device manufacturer shall obtain certification by the Division under this Article before offering an ignition interlock device model for installation under Arizona law.

**B.** After receiving Division certification for an ignition interlock device model under R17-5-604, the ignition interlock device manufacturer is effectively certified by the Division to offer its certified ignition interlock device model for installation under Arizona law.

**C.** An ignition interlock device manufacturer shall submit a new application to the Division under R17-5-604 for the certification of each new ignition interlock device model the manufacturer intends to offer for installation.

**D.** Manufacturer certification issued by the Division under this Article shall automatically expire if:

1. The manufacturer no longer provides at least one currently certified ignition interlock device model for installation under Arizona law; and
2. The manufacturer has no pending application on file with the Division for the certification of a device under R17-5-604.

**E.** Once a manufacturer's certification expires, the manufacturer may reapply for certification by submitting a new application to the Division for the certification of a device under R17-5-604.

**R17-5-603. Device Requirements, Technical Specifications, and Standards for Setup and Calibration**

**A.** Accuracy standards. The startup set point value for an ignition interlock device shall be an alcohol concentration of 0.030 g/210 liters of breath. The accuracy of a device shall be 0.030 g/210 liters plus or minus 0.010 g/210 liters. The accuracy shall be determined by analysis of an external standard generated by a reference sample device.

**B.** Alveolar breath sample. A device shall have a demonstrable feature designed to assure that a breath sample measured is essentially alveolar.

**C.** Specificity. A test of alcohol-free samples shall not yield a positive result. Endogenously produced substances capable of being present in the breath shall not yield or significantly contribute to a positive result.

**D.** Temperature. A device shall meet the requirements of subsection (A) when used at ambient temperatures of -20° Celsius to 83° Celsius.

**E.** Anticircumvention standards. A device shall be designed so that anticircumvention features will be difficult to bypass.

1. Anticircumvention provisions shall include, but are not limited to, prevention or preservation of any evidence of cheating by attempting to use a false or filtered breath sample or electronically bypassing the breath sampling requirements of a device.
2. A device shall use special seals or other methods that reveal attempts to bypass lawful device operation.

**F.** Operational features.

1. A device shall allow a free restart of a motor vehicle's ignition, within three minutes after the ignition is switched off, without requiring another breath alcohol test.
2. A device shall automatically purge alcohol before allowing analysis.
3. A device shall have a data storage system with the capacity to sufficiently record and maintain a record of the participant's daily driving activities that occur between each regularly scheduled accuracy and compliance check referenced under R17-5-610 and R17-5-706. All daily driving activity records in the device's data storage system shall be maintained by the installer and the service center and made available to the Division upon request as provided under R17-5-612.
4. A device shall use the most current version of the manufacturer's software and firmware to ensure compliance with this Article and any other applicable rule or statute. The manufacturer's software and firmware:
   a. Shall require device settings and operational features to include, but are not limited to, sample delivery requirements, startup and retest set points, free restart, rolling retest requirements, violation settings and lock-out conditions; and
   b. Shall not allow modification of the device settings or operational features by a service center or service representative unless the Division approves the modification under subsection (G).
5. A device shall record all emergency bypasses in its data storage system.
6. A device shall require a participant to perform a rolling retest within five to 15 minutes after the initial test required to start an engine. The device shall continuously require additional rolling retests at random intervals of up to 45 minutes after each previously requested retest.
   a. A device shall emit a warning light, tone, or both, to alert a participant that a rolling retest is required.
   b. A device shall require a participant to perform a new test to restart an engine if it is inadvertently switched off during or after a rolling retest warning.
   c. A device shall use the startup set point value as its retest set point value.

d. A device shall record, in its data storage system, the result of each rolling retest performed by a participant.
e. A device shall immediately require another rolling retest each time a participant refuses to perform a requested rolling retest.

7. Until a participant successfully performs a rolling retest, or the engine is switched off, a device shall record in its data storage system, each subsequent refusal of the participant to perform the requested rolling retest.
8. Upon recording a violation of A.R.S. Title 28, Chapter 4, Article 5, the device shall emit a unique cue, either auditory, visual, or both, to warn a participant that the device will enter into a lock-out condition in 72 hours unless reset by the installer.
9. When a violation results in a lock-out condition, the device shall:
   a. Immobilize the participant's vehicle;
   b. Uniquely record the event in the data storage system; and
   c. Require a violation reset by the installer.

**G.** Modification. No modification shall be made to the design or operational concept of a device after the Division has certified the device for installation under Arizona law.

1. A software or firmware update required to maintain a device is permissible if the update does not modify the design or operational concept of the device.
2. Replacement, substitution, or repair of a part required to maintain a device is permissible if the part does not modify the design or operational concept of the device.
3. If a manufacturer determines that an existing Division-certified ignition interlock device model requires a modification that may affect the operational concept of a device, the manufacturer shall immediately notify the Division.

**~~R17-5-602.~~R17-5-604. Ignition Interlock Device Certification; Application Requirements**

**A.** A ~~participant shall have installed in a motor vehicle~~ manufacturer shall offer for installation only an ignition interlock device that is certified by the Division under ~~R17-5-602 and R17-5-603~~ this Section.

**B.** For certification of an ignition interlock device model, a manufacturer shall submit to the Division a properly completed application form that provides:

1. The manufacturer's name;
2. The manufacturer's business address and telephone number;
3. The manufacturer's status as a sole proprietorship, partnership, limited liability company, or corporation;
4. The name of the sole proprietor or of each partner, officer, director, manager, member, agent, or 20% or more stockholder;
5. The name and model number of the ignition interlock device and the name under which the ignition interlock device will be marketed; and
6. The following statements, signed by an authorized representative ~~for~~ of the manufacturer and acknowledged by a notary public or Division agent:
   a. A statement that all information provided on the application form ~~and attachments~~, including all information provided on any attachment to the application form, ~~are~~ is complete, true, and correct;
   b. A statement that the manufacturer agrees to indemnify and hold harmless the state of Arizona~~, the Division,~~ and any department, division, agency, officer, employee, or agent of the state of Arizona ~~harmless~~ from all liability for:
      i. Damage to property or injury to people arising, directly or indirectly, out of any act or omission by the manufacturer or its authorized installer relating to ~~use~~ the installation and operation of the ignition interlock device; and
      ii. All court costs, expenses of litigation, and reasonable attorneys' fees;
   c. A statement that the manufacturer agrees to comply with ~~the alcohol setpoint established by the Division for certified ignition interlock devices and printed on the application form~~ all requirements under this Article; and
   d. A statement that the manufacturer agrees to ~~comply with the requirements of R17-5-601 through R17-5-609~~ immediately notify the Division of any change to the information provided on the application form.

**C.** ~~With the application form, the~~ A manufacturer shall submit the following additional items with the application form:

1. A document that provides a detailed description of the ignition interlock device and a photograph, drawing, or other graphic depiction of the device;
2. A document that contains the complete technical specifications ~~of~~ for the accuracy, reliability, security, data collection, ~~and~~ recording, and tamper detection capabilities of the ignition interlock device;
3. An independent laboratory's report that:
   a. Presents supporting data ~~that~~ to demonstrate that the ignition interlock device meets or exceeds the test results required by Sections 1 and 2 of the NHTSA specifications published at 57 FR 11772 to 11787, April 7, 1992. The NHTSA specifications are incorporated by reference and are on file with the Division and the ~~Office of the Secretary of State. The NHTSA specifications are also available from the Office of Research & Traffic Records, Room 6240 (NTS-30),~~ NHTSA Office of Research & Technology (NTS-131), 400 7th ~~Street~~ St. S.W., Washington, D.C. 20590~~, Telephone: (202) 366-5593~~. This incorporation by reference contains no future editions or

amendments;
b. Provides the independent laboratory's name, address, and telephone number; and
c. Provides the name and model number of the ignition interlock device tested;
4. A laboratory certification form, signed by an authorized representative of the independent laboratory that prepared the report required ~~in~~ under subsection (C)(3) and acknowledged by a notary public or Division agent, that states:
a. The laboratory is not owned or operated by a manufacturer and no other conflict of interest exists;
b. The laboratory tested the ignition interlock device in accordance with Sections 1 and 2 of the NHTSA specifications;
c. The laboratory confirms that the ignition interlock device ~~met or exceeded~~ meets or exceeds the test results required under Sections 1 and 2 of the NHTSA specifications;
d. The laboratory used properly maintained equipment and trained personnel to test the ignition interlock device; and
e. The laboratory presented accurate test results to the Division;
5. A list of all authorized installers of the ignition interlock device, including the name, location, telephone number, contact person, and hours of operation of each authorized installer;
6. ~~The~~ A copy of the complete written instructions ~~provided~~ the manufacturer will provide to its authorized installers under R17-5-609 for ~~use~~ installation and operation of the ignition interlock device ~~that include the requirement to affix a warning label, conforming to the design printed on the application form by the Division, to each installed certified ignition interlock device~~ for which the manufacturer seeks certification. The written instructions shall include a requirement for the installer to affix, to each certified ignition interlock device installed, a warning label that conforms to the criteria prescribed under R17-5-609, as illustrated on the application form provided by the Division;
7. ~~The~~ A copy of the complete written instructions ~~provided~~ the Manufacturer shall provide to its authorized installers under R17-5-609 for distribution under R17-5-704 to participants and other operators of a vehicle equipped with the ignition interlock device for which the manufacturer seeks certification; and
8. A certificate of insurance, issued by an insurance company authorized to transact business in Arizona, specifying:
a. A product liability policy with a current effective date;
b. The name and model number of the ignition interlock device model covered by the policy;
c. ~~A policy limit~~ Policy coverage of at least $1,000,000;
d. The manufacturer as the insured and the ~~Division~~ state of Arizona as an additional insured;
e. Product liability coverage for defects in manufacture, materials, design, calibration, ~~and use~~ installation, and operation of the ignition interlock device; and
f. The insurance company will notify the Division at least 30 days before canceling the product liability policy.

**R17-5-605. Application Processing; Time-frames; Exception**

**A.** The Division shall process an application for certification under this Article, and Article 7, only if an applicant meets all applicable application requirements.

**B.** The Division shall, within 10 days of receiving an application for certification, provide notice to the applicant that the application is either complete or incomplete.
1. The date of receipt is the date the Division stamps on the application when received.
2. If an application is incomplete, the notice shall specifically identify what required information is missing.

**C.** An applicant with an incomplete application shall provide all missing information to the Division within 15 days of the date indicated on the notice provided by the Division under subsection (B).
1. After receiving all of the required information, the Division shall notify the applicant that the application is complete.
2. The Division may deny certification if the applicant fails to provide the required information within 10 days of the date indicated on the notice.

**D.** Except as provided under subsection (F), the Director shall render a decision on an application for certification under this Article or Article 7, within 45 days of the date indicated on the notice acknowledging receipt of a complete application, provided to the applicant under subsections (B) or (C).

**E.** For the purpose of A.R.S. § 41-1073, the Division establishes the following time-frames for processing an application for certification under this Article or Article 7:
1. Administrative completeness review time-frame: 15 days.
2. Substantive review time-frame: 30 days.
3. Overall time-frame: 45 days.

**F.** Established time-frames may be adjusted by the Division as needed to obtain all external agency approvals required for certifying a new ignition interlock device model submitted by a manufacturer under R17-5-604.

**~~R17-5-603.~~R17-5-606. Application Completeness; ~~Refusal to Certify an~~ Denial of Ignition Interlock Device Certification; Hearing~~.~~**

**A.** An application for certification of an ignition interlock device model is complete when the Division receives:
1. ~~A~~ From the manufacturer, a properly ~~filled out~~ prepared application form~~.~~;

2. ~~All~~ From the manufacturer, all additional items required ~~by R17-5-602(C),~~ under R17-5-604(C); and
3. ~~An outside reviewer's~~ From the Arizona Department of Public Safety, under A.R.S. § 28-1462, written confirmation or disapproval of the independent laboratory's report that the ignition interlock device meets ~~the~~ NHTSA specifications. ~~The Division shall choose an agency or individual outside the Division to review an independent laboratory's report.~~

**B.** The ~~Division~~ Director shall ~~refuse to certify~~ deny an application for certification of an ignition interlock device model if all requirements of subsection (A) are not met, or upon finding any of the following:
1. ~~A defect in~~ The design, materials, or workmanship contains a defect that causes the ignition interlock device model to fail to function as intended;
2. ~~Termination or cancellation of the~~ The manufacturer's liability insurance coverage is terminated or canceled;
3. The manufacturer no longer ~~provides~~ offers the ignition interlock device model for installation under Arizona law;
4. ~~False or inaccurate information provided by the~~ The manufacturer or independent laboratory~~,~~ provided false or inaccurate information to the Division relating to the performance of the ignition interlock device model; ~~or~~
5. ~~Modification of the~~ The components, design, or ~~installing~~ installation and operating instructions have undergone a modification that causes the ignition interlock device ~~no longer to satisfy the~~ model to be out of compliance with NHTSA specifications~~.~~; or
6. The Division receives a report of device disapproval from an independent laboratory or other external reviewer.

**C.** The Division shall ~~send~~ mail ~~written notification~~ to the manufacturer, written notification of the certification or denial of an ignition interlock device model ~~or of refusal to certify the device~~. ~~The~~ A notice ~~of refusal to certify~~ denying certification of an ignition interlock device model shall specify the basis for the ~~refusal~~ denial and indicate that the applicant may, within 15 days of the date on the notice, request a hearing on the Director's decision to deny certification by filing a written request with the Division's Executive Hearing Office as prescribed under 17 A.A.C. 1, Article 5.
1. ~~The manufacturer shall address any request for a hearing on the refusal to certify an ignition interlock device to the Arizona Department of Transportation, Motor Vehicle Division, Executive Hearing Office, 1801 West Jefferson, Mail Drop 507M, Phoenix, Arizona 85007. The Division must receive the hearing request within 15 days after the date of mailing of the notice of refusal.~~
2. ~~A.R.S. §§ 41-1061 through 41-1067 and R17-4-901 through R17-4-912 apply to a hearing on the refusal to certify an ignition interlock device.~~

**D.** If a manufacturer timely requests a hearing on the Director's decision to deny certification, the Division's Executive Hearing Office shall conduct the hearing as provided under A.R.S. Title 41, Chapter 6, Article 6, and 17 A.A.C. 1, Article 5.

**~~R17-5-604.~~R17-5-607. Cancellation of Certification; Hearing**

**A.** The ~~Division~~ Director shall cancel ~~the certification of~~ an ignition interlock device model certification and remove ~~it from~~ the device from its list of certified ignition interlock devices upon finding any of the following:
1. ~~A defect in~~ The design, materials, or workmanship contains a defect that causes the ignition interlock device model to fail to function as intended;
2. ~~Termination or cancellation of the~~ The manufacturer's liability insurance coverage is terminated or canceled;
3. The manufacturer no longer ~~provides~~ offers the ignition interlock device model for installation under Arizona law;
4. ~~False or inaccurate information provided by the~~ The manufacturer or independent laboratory~~,~~ provided false or inaccurate information to the Division relating to the performance of the ignition interlock device model;
5. ~~Modification of the~~ The components, design, or ~~installing~~ installation and operating instructions have undergone a modification that causes the ignition interlock device model ~~no longer to satisfy the~~ to be out of compliance with NHTSA specifications;
6. ~~A voluntary request by the manufacturer to cancel the~~ The manufacturer instructs the Division to cancel its certification of the ignition interlock device model; or
7. The ~~manufacturer's noncompliance~~ manufacturer, its authorized installer, or the device does not comply with ~~R17-5-605 through R17-5-609~~ this Article or any other applicable rule or statute~~; or~~.
8. ~~An authorized installer's noncompliance with R17-5-606 through R17-5-609.~~

**B.** The Division, upon finding any of the conditions described under subsection (A), shall ~~send~~ mail to the manufacturer ~~by certified mail, return receipt requested, the~~ a notice and order of cancellation of ~~the~~ certification ~~of an~~ for the specific ignition interlock device model. The notice and order of cancellation shall:
1. Specify the basis for the action~~.~~;; and
2. ~~State the Division will schedule a hearing~~ State that the manufacturer may, within 15 days of the date on the notice, file a written request for a hearing with the Division's Executive Hearing Office to show cause as to why the ignition interlock device certification should not be cancelled.

**C.** ~~The notice of hearing shall be sent to the manufacturer by certified mail, return receipt requested~~ If a hearing to show cause is timely requested, the Division's Executive Hearing Office shall conduct the hearing as prescribed under A.R.S. Title 41, Chapter 6, Article 6, and 17 A.A.C. 1, Article 5.
1. ~~The notice of hearing shall include the date, time, and place for the manufacturer's representative to appear and show cause why the ignition interlock device certification should not be cancelled.~~

2. ~~A.R.S. §§ 41-1061 through 41-1067, A.A.C. R17-1-501, R17-1-504 through R17-1-511, and R17-1-513 apply to the show cause hearing.~~

**D.** Within 60 days after the effective date of an order of cancellation, the manufacturer shall ~~do one of the following at the manufacturer's cost:~~, at the manufacturer's own expense, ensure the removal of all decertified ignition interlock devices and facilitate the replacement of each device with a certified ignition interlock device.
1. ~~Remove all decertified ignition interlock devices and install certified ignition interlock devices,~~
2. ~~Remove all decertified ignition interlock devices and have a second manufacturer provide and install certified ignition interlock devices, or~~
3. ~~Have a second manufacturer remove all decertified ignition interlock devices and provide and install certified ignition interlock devices.~~

**E.** ~~The Division shall not accept an application for certification of an ignition interlock device from a manufacturer that fails to comply with subsection (D).~~ The manufacturer of a previously decertified ignition interlock device model may reapply to the Division for certification of the ignition interlock device model under R17-5-604.

**~~F.~~** ~~A manufacturer of a previously decertified ignition interlock device model may apply to have the ignition interlock device model recertified by complying with R17-5-602.~~

**~~R17-5-605.~~R17-5-608. Modification of a Certified Ignition Interlock Device Model**

**A.** A manufacturer shall notify the Division in writing at least 10 days before a material modification is made to a certified ignition interlock device model.

**B.** Before providing a previously certified but materially modified ignition interlock device model for installation in a motor vehicle under an order of an Arizona court or the Division, a manufacturer shall:
1. Submit to the Division a completed application form and all additional items required ~~by R17-5-602(C),~~ under R17-5-604(C); and
2. Obtain certification of the materially modified ignition interlock device from the Division.

**C.** The Division's certification of a materially modified ignition interlock device model does not affect the original certification of the unmodified model.

**~~R17-5-606.~~R17-5-609. Manufacturer Referral to ~~Authorized~~ Division-certified Installers; Manufacturer Oversight of its Authorized Installers**

**A.** A manufacturer shall refer a participant only to ~~an authorized~~ a Division-certified installer.

**B.** A manufacturer shall provide the Division with a toll-free telephone number for a participant to call to obtain names, locations, telephone numbers, contact people, and hours of operation ~~of~~ for its authorized installers.

**C.** A manufacturer shall ensure that ~~an~~ its authorized installer follows the ~~use~~ installation and operation procedures established by the manufacturer.

**D.** A manufacturer shall ensure that ~~an~~ its authorized installer ~~has the~~ receives and maintains all necessary training and skills ~~specified by the manufacturer~~ required to install, troubleshoot, examine, and verify proper operation of the certified ignition interlock device.

**E.** A manufacturer shall ensure that ~~an~~ its authorized installer:
1. Complies with the manufacturer's procedures for removing a certified ignition interlock device from a vehicle, and
2. ~~Notifies~~ Electronically notifies the Division ~~by certified mail, within 10 days~~ within 24 hours after removing a certified ignition interlock device~~, of the device~~'s removal.

**F.** A manufacturer shall ensure that ~~an~~ its authorized installer ~~provides~~ distributes to every participant, and makes available for every person operating a motor vehicle equipped with a certified ignition interlock device, ~~with~~ the manufacturer's written instructions for the following:
1. Operating a motor vehicle equipped with the certified ignition interlock device;
2. Cleaning and caring for the certified ignition interlock device; and
3. ~~Dealing with~~ Identifying and addressing any vehicle malfunctions or repairs that may affect the certified ignition interlock device~~, including a list of vehicle malfunctions or repairs that affect the device~~.

**G.** A manufacturer shall ensure that ~~an~~ its authorized installer provides to every participant, and makes available for any person operating a motor vehicle equipped with a certified ignition interlock device, the manufacturer's specified training in how to operate a motor vehicle equipped with the device.

**H.** A manufacturer or installer shall provide a warning label, for each certified ignition interlock device installed, which shall:
1. Be of a size appropriate to each device model;
2. Have an orange background; and
3. Contain the following language in black lettering: "Warning! Any person tampering with, circumventing, or otherwise misusing this Ignition Interlock Device, is guilty of a Class 1 misdemeanor."

**~~H.~~I.** A manufacturer shall ensure that ~~an~~ its authorized installer affixes conspicuously to each installed certified ignition interlock device ~~a warning label conforming to the design adopted by the Division~~ the warning label described under subsection (H).

**~~R17-5-607.~~R17-5-610. Installation Verification; Accuracy Check; Noncompliance ~~Report~~ and Removal Reporting**

~~**A.** A manufacturer shall ensure that an authorized installer:~~
- ~~1. Complies with the manufacturer's procedures for installing a certified ignition interlock device, and~~
- ~~2. Provides a completed and signed Arizona ignition interlock installation verification form (Appendix A) to the participant.~~

~~**B.** A manufacturer shall ensure that an authorized installer schedules a participant for accuracy checks as follows:~~
- ~~1. 30 days, 60 days, and 90 days after installation of a certified ignition interlock device; and~~
- ~~2. After the 90-day accuracy check, at least every 60 days.~~

~~**C.** A manufacturer shall ensure that an authorized installer:~~
- ~~1. Submits to the Division within 10 days after an accuracy check of an installed certified ignition interlock device:~~
  - ~~a. A completed and signed Arizona ignition interlock accuracy check form (Appendix B); or~~
  - ~~b. If the certified ignition interlock device has signs of tampering, circumvention, or misuse, a completed and signed Arizona ignition interlock noncompliance report (Appendix C) plus the completed and signed Arizona ignition interlock accuracy check form; or~~
- ~~2. Submits to the Division a completed and signed Arizona ignition interlock noncompliance report form within 10 days after a scheduled accuracy check of an installed certified ignition interlock device when a participant fails to present the motor vehicle with the installed certified ignition interlock device within five days after the scheduled accuracy check.~~

~~**D.** A manufacturer shall ensure that the Arizona ignition interlock accuracy check form completed by the authorized installer:~~
- ~~1. States the calibration of the certified ignition interlock device before recalibration,~~
- ~~2. Has a data logger sheet attached, and~~
- ~~3. Is signed by the authorized installer.~~

**A.** A participant shall have installed in a motor vehicle, only an ignition interlock device certified by the Division under R17-5-604.

**B.** A manufacturer shall comply, and ensure that its authorized installer complies, with its written procedures for the installation of a certified ignition interlock device.

**C.** Certified ignition interlock device installation verification.
- 1. A manufacturer shall electronically transmit, or ensure that its authorized installer electronically transmits, a Certified Ignition Interlock Device Summarized Reporting Record to the Division within 24 hours of installing a certified ignition interlock device.
- 2. The electronic Certified Ignition Interlock Device Summarized Reporting Record for installation verification shall contain all of the following information:
  - a. Installer ID;
  - b. Participant's full name (first, middle, last and suffix);
  - c. Date of birth;
  - d. Driver license or customer number;
  - e. Report date;
  - f. Install date;
  - g. Removal date; and
  - h. Report Type.

**D.** Certified ignition interlock device accuracy and compliance check.
- 1. A manufacturer shall ensure that its authorized installer schedules a participant for accuracy and compliance checks as follows:
  - a. 30 days, 60 days, and 90 days after installation of a certified ignition interlock device; and
  - b. At least once every 60 days after the 90-day accuracy and compliance check.
- 2. A manufacturer shall electronically transmit, or ensure that its authorized installer electronically transmits, a Certified Ignition Interlock Device Summarized Reporting Record to the Division within 24 hours after performing an accuracy and compliance check on an installed certified ignition interlock device.
- 3. The electronic Certified Ignition Interlock Device Summarized Reporting Record for the accuracy and compliance check shall contain all of the following information:
  - a. Installer ID;
  - b. Participant's full name (first, middle, last and suffix);
  - c. Date of birth;
  - d. Driver license or customer number;
  - e. Report date;
  - f. Install date;
  - g. Removal date;
  - h. Report Type; and

i. Noncompliance code and breath alcohol concentration violation count as applicable.

**E.** Certified ignition interlock device noncompliance report.

1. A manufacturer shall electronically transmit, or ensure that its authorized installer electronically transmits, a Certified Ignition Interlock Device Summarized Reporting Record to the Division, within 24 hours after conducting an accuracy and compliance check, when an installed certified ignition interlock device displays evidence of tampering, circumvention, or misuse.
2. The electronic Certified Ignition Interlock Device Summarized Reporting Record for noncompliance shall indicate the condition of noncompliance and contain all of the following information:
   a. Installer ID;
   b. Participant's full name (first, middle, last and suffix);
   c. Date of birth;
   d. Driver license or customer number;
   e. Report date;
   f. Install date;
   g. Removal date;
   h. Report Type; and
   i. Noncompliance code and breath alcohol concentration violation count as applicable.

**F.** Certified ignition interlock device removal report.

1. A manufacturer shall electronically transmit, or ensure that its authorized installer electronically transmits, a Certified Ignition Interlock Device Summarized Reporting Record to the Division within 24 hours if a certified ignition interlock device is removed before the end of a participant's certified ignition interlock device requirement period.
2. The electronic Certified Ignition Interlock Device Summarized Reporting Record for removal of a device shall indicate the condition of noncompliance and contain all of the following information:
   a. Installer ID;
   b. Participant's full name (first, middle, last and suffix);
   c. Date of birth;
   d. Driver license or customer number;
   e. Report date;
   f. Install date;
   g. Removal date;
   h. Report Type; and
   i. Noncompliance code and breath alcohol concentration violation count as applicable.

**Appendix A. ~~Ignition Interlock Installation Verification~~ Repealed**

~~ARIZONA~~
~~IGNITION INTERLOCK INSTALLATION VERIFICATION~~
~~As Ordered by the Court or the Division~~

~~COURT OR DIVISION DOCKET No.: _____ TODAY'S DATE _____~~

~~PARTICIPANT NAME: _____~~
~~ADDRESS: _____~~
~~CITY _____ ST _____ ZIP _____~~
~~PHONE NUMBER: _____~~
~~DRIVER LICENSE No OR SS No.: _____~~

~~INSTALLER NAME: _____~~
~~ADDRESS: _____~~
~~CITY _____ ST _____ ZIP _____~~
~~PHONE NUMBER: _____~~
~~IGNITION INTERLOCK DEVICE MANUFACTURER and MODEL TYPE: _____~~
~~_____~~
~~IGNITION INTERLOCK DEVICE SERIAL NUMBER(s): _____~~

~~VEHICLE IDENTIFICATION INFORMATION:~~
~~TITLE OWNER: _____ TITLE No.: _____~~
~~Make: _____ Model _____ VIN _____~~
~~Color _____ Year _____ License Plate No. _____~~
~~Odometer reading: _____~~

~~PARTICIPANT EDUCATION CHECKLIST~~
~~_____ I have been instructed on the use of the system.~~

~~_____ I understand how to power the system on and off.~~
~~_____ I have delivered and passed a proper breath sample.~~
~~_____ I have delivered and understand an abort test.~~
~~_____ I understand how the alcohol retest feature works.~~
~~_____ I understand that if I smoke cigarettes or drink alcohol before testing that I may receive a sensitive or fail reading.~~
~~_____ I have been informed of how to obtain service for my system or to have questions answered.~~
~~_____ I have received my operator's manual.~~
~~_____ I have been informed of the penalties for tampering with, circumventing, or misusing the system.~~
~~_____ I have been informed of what happens after failing three breath attempts.~~
~~_____ I have been informed of what happens after failing "rolling retest."~~

~~MONITORING:~~
~~Your next monitoring check is _____. Your ignition system will remind you that you are due to make an appointment. If you fail to make an appointment, your ignition interlock device will shut down and you will be unable to start your car. It will be your responsibility to have your car towed to the Service Center. If you fail to appear you may be found in noncompliance, and your driver license can be suspended for at least one year under A.R.S. § 28-1463.~~
~~Signature of Participant: _____ Date_____~~

~~Signature of Installer: _____ Date_____~~

~~Attach copy of Court Order or Division Order for Installation of Ignition Interlock Device.~~

**Appendix B. ~~Ignition Interlock Accuracy Check~~ Repealed**

~~ARIZONA~~
~~IGNITION INTERLOCK~~
~~ACCURACY CHECK~~

~~DATE: _____~~
~~INSTALLER_____~~
~~MANUFACTURER and MODEL TYPE: _____~~
~~SERIAL NUMBER(s): _____~~
~~MONITORING CHECK No. _____~~

~~PARTICIPANT NAME_____~~
~~DATE OF BIRTH: _____~~
~~DRIVER LICENSE No.: _____~~

~~VEHICLE LICENSE PLATE No.: _____~~
~~ODOMETER READING: _____~~
~~CALIBRATION WAS _____ BEFORE RECALIBRATION.~~
~~THE SYSTEM IS NOW IN CALIBRATION: ___~~
~~THE SYSTEM HAS BEEN INSPECTED AND IS FUNCTIONING PROPERLY. ____~~
~~THERE IS NO EVIDENCE OF ATTEMPTED TAMPERING, CIRCUMVENTION, OR MISUSE. ____~~
~~(IF THERE ARE SIGNS OF TAMPERING, CIRCUMVENTION, OR MISUSE, COMPLETE "NONCOMPLIANCE REPORT")~~

~~COMMENTS:~~
_____
_____
_____
_____
_____
_____
_____

~~Your next monitoring check is _____. Your ignition system will remind you that you are due to make an appointment. If you fail to make an appointment, your ignition interlock device will shut down and you will be unable to start your car. It will be your responsibility to have your car towed to the Service Center. If you fail to appear you may be found in noncompliance, and your driver license can be suspended for one year. If convicted of tampering with the ignition interlock device you can be required to use the device for additional time. A.R.S. §§ 28-1463 and 28-1464.~~

~~Signature of Participant_____ Date: _____~~

~~Signature of Installer: _____ Date: _____~~

~~ATTACH COPY OF DATA LOGGER SHEET AND SEND TO:~~
~~MOTOR VEHICLE DIVISION, DRIVER IMPROVEMENT UNIT~~
~~PO BOX 2100, MAIL DROP 530M~~
~~PHOENIX, AZ 85001-2100~~

**Appendix C. ~~Ignition Interlock Noncompliance Report~~ Repealed**

~~ARIZONA~~
~~IGNITION INTERLOCK~~
~~NONCOMPLIANCE REPORT~~

~~DATE: _____~~
~~INSTALLER: _____~~
~~MANUFACTURER and MODEL TYPE: _____~~
~~SERIAL NUMBER(s): _____~~
~~MONITORING CHECK No.: _____~~

~~PARTICIPANT NAME: _____~~
~~DATE OF BIRTH: _____~~
~~DRIVER LICENSE No.: _____~~

~~VEHICLE LICENSE PLATE No.: _____~~

~~THE PARTICIPANT FAILED TO KEEP APPOINTMENT: _____~~
~~Attempts have been made to contact customer on:~~

~~_____~~
~~Date Time~~
~~_____~~
~~Date Time~~
~~_____~~
~~Date Time~~

~~THE DEVICE SHOWS EVIDENCE OF TAMPERING, CIRCUMVENTION, OR MISUSE: _____~~
~~Explanation:~~
~~_____~~
~~_____~~
~~_____~~
~~_____~~
~~_____~~
~~_____~~
~~_____~~
~~_____~~
~~_____~~
~~_____~~
~~_____~~

~~Signature of Installer: _____ Date: _____~~

~~SEND TO:~~
~~MOTOR VEHICLE DIVISION, DRIVER IMPROVEMENT UNIT~~
~~PO BOX 2100, MAIL DROP 530M~~
~~PHOENIX, AZ 85001-2100~~

**~~R17-5-608.~~R17-5-611. Emergency Assistance by Manufacturers and Authorized Installers; Continuity of Service to Participants**

~~**A.** A manufacturer shall ensure that an authorized installer provides a participant with a 24-hour emergency phone number for assistance in the event the certified ignition interlock device fails or the vehicle experiences problems related to the ignition interlock device's operation. Emergency assistance provided by the authorized installer shall include technical information, towing service, and road service.~~

~~1. If the participant's motor vehicle is located not more than 50 miles from the authorized installer, emergency assistance shall be provided within two hours after the call for assistance.~~

~~2. If the participant's motor vehicle is located not more than 100 miles from the authorized installer, emergency assistance shall be provided within four hours after the call for assistance.~~

~~3. The authorized installer shall make the certified ignition interlock device functional within 48 hours after a participant's emergency assistance call or shall replace the device.~~

**A.** A manufacturer shall ensure that its authorized installer provides to each participant a 24-hour emergency phone number for assistance in the event a certified ignition interlock device fails to operate properly or a vehicle experiences a problem relating to the installation, operation, or failure of a certified ignition interlock device.

1. Within two hours after receiving a participant's call for emergency assistance, if the authorized installer determines that a vehicle is experiencing a problem relating to the installation, operation, or failure of a certified ignition interlock device, the authorized installer shall either:
   a. Provide telephonically, the technical information required for the participant to resolve the issue; or

b. Provide or arrange for appropriate towing or roadside assistance services if unable to resolve the issue telephonically.

2. Within 48 hours after receiving a participant's call for emergency assistance, the authorized installer shall either:
   a. Make the certified ignition interlock device functional; or
   b. Replace the certified ignition interlock device.

**B.** A manufacturer shall ensure uninterrupted service to a participant for the duration of the participant's ~~Arizona court order or Division order.~~ certified ignition interlock device requirement, which shall include facilitating the immediate replacement of an authorized installer if the installer goes out of business or its certification is cancelled by the Division under R17-5-708.

1. If a manufacturer terminates ~~an~~ its authorized installer's appointment, or the Division cancels the installer's certification under R17-5-708, the manufacturer shall:
   a. Obtain participant records from ~~the former~~ its formerly authorized installer; and
   b. Provide the participant records to a new authorized installer for retention according to ~~R17-5-609~~ R17-5-612; or
   c. ~~If the manufacturer does not appoint a new authorized installer, the manufacturer shall retain~~ Retain the participant records according to ~~R17-5-609~~ R17-5-612, if a new authorized installer is not appointed.
2. ~~A manufacturer shall~~ If a manufacturer appoints a new authorized installer, the manufacturer shall:
   ~~a. Ensure that an authorized installer has a permanent facility within 100 miles of the Arizona residence of each participant with an installed certified ignition interlock device provided by the manufacturer;~~
   ~~b. Ensure that an authorized installer uses a mobile facility for scheduled accuracy checks at specified locations within 100 miles of the Arizona residence of each participant with an installed certified ignition interlock device provided by the manufacturer; or~~
   ~~c. Pay to remove a participant's installed certified ignition interlock device and install a certified ignition interlock device, including a model provided by a second manufacturer, that has an authorized installer with:~~
      ~~i. A permanent facility within 100 miles of the participant's Arizona residence, or~~
      ~~ii. A mobile facility for scheduled accuracy checks at a specified location within 100 miles of the participant's Arizona residence.~~
   a. Ensure that the new authorized installer operates either:
      i. A mobile service center that is located within 75 miles of the Arizona residence of each participant with an installed certified ignition interlock device provided by the manufacturer; or
      ii. A service center that is a permanent facility located within 125 miles of the Arizona residence of each participant with an installed certified ignition interlock device provided by the manufacturer; and
   b. Notify each participant affected by the appointment of the new authorized installer at least 30 days before the appointment becomes effective.
3. ~~A manufacturer shall notify a participant of the appointment of a new authorized installer or replacement of a certified ignition interlock device at least 30 days before the new authorized installer's appointment becomes effective or replacement of the device occurs.~~
3. If a manufacturer does not appoint a new authorized installer, or its new authorized installer cannot provide service as prescribed under subsection (2), the manufacturer, at no cost to the participant, shall:
   a. Provide written notification to all participants affected by the change of authorized installers at least 30 days before the authorized installer is to discontinue service. The written notification shall inform the participant of the manufacturer's responsibility to facilitate removal and replacement of the certified ignition interlock device and shall provide all of the instructions necessary for the participant to successfully exchange the device;
   b. Remove the device from the vehicle of each affected participant; and
   c. Facilitate the replacement of each device through a manufacturer with an authorized installer that can provide service as prescribed under subsection (2).
4. ~~Within 10 days after a change in the list of authorized installers submitted to the Division by a manufacturer, the manufacturer shall submit an updated list of authorized installers to the Division.~~ A manufacturer shall notify the Division within 72 hours of replacing its authorized installer.
5. A manufacturer shall submit to the Division an updated list of its authorized installers within 10 days after making a change to the list provided to the Division under R17-5-604.

**C.** Except in an emergency situation, a manufacturer or its authorized installer shall not remove another manufacturer's certified ignition interlock device without the express permission of that manufacturer.

1. If in an emergency situation a manufacturer or its authorized installer removes another manufacturer's certified ignition interlock device, that manufacturer or authorized installer shall return the device to the original installer within 72 hours of the emergency removal; and
2. The original installer, upon receipt of the device, shall provide to the Division an electronic report of the device removal under R17-5-610, which shall include the transmission of all data stored in its data storage system.

**D.** A manufacturer shall facilitate the immediate replacement of its authorized installer's service center if the service center goes out of business or its Division certification is cancelled under R17-5-708. The manufacturer shall notify the Division

within 72 hours of replacing a service center.

1. If an out-of-business or cancelled service center is replaced, the manufacturer shall make all reasonable efforts to obtain, from the service center being replaced, all participant records and data required to be retained under R17-5-612. The records shall be provided to, and maintained by, the new service center.
2. If an out-of-business or cancelled service center is not replaced, the manufacturer shall retain the records and data as required under R17-5-612. The Division shall be notified of this event within 72 hours.
   a. The manufacturer shall facilitate removal of all installed certified ignition interlock devices no longer serviced by the out-of-business or cancelled service center, and shall bear the cost of replacing each device with a serviceable certified ignition interlock device, even if the replacement device must be provided through an alternate manufacturer.
   b. The manufacturer shall, within 30 days, make a reasonable effort to notify its customers of the change of service center or replacement of a device.
3. If neither subsection (1) nor (2) can be accomplished, the manufacturer shall, within 60 days:
   a. Notify its customers and the Division that service will be terminated; and
   b. Remove each device at no cost to the customer.

**~~R17-5-609.~~R17-5-612. Records Retention; Submission of Copies and ~~Monthly~~ Quarterly Reports; Periodic ~~Audits~~ Inspections**

**A.** Records retention. A manufacturer shall retain, or ensure that ~~an~~ its authorized installer ~~or the manufacturer~~ retains, a participant's records for ~~one year~~ five years after the removal of a certified ignition interlock device. The retained records shall consist of every document relating to ~~use~~ installation and operation of the certified ignition interlock device.

**B.** Copies of records and ~~monthly~~ quarterly reports.

1. A manufacturer shall ensure that ~~an~~ its authorized installer or the manufacturer provides copies of participants' records to the Division within 10 days after Division personnel make a request for copies of records, including records ~~of use~~ relating to installation and operation of the certified ignition interlock device.
2. ~~A manufacturer shall ensure that an authorized installer submits a report to the Division so the Division receives the report by the 10th day of each month. The monthly report shall contain the following information:~~
   ~~a. The number of certified ignition interlock devices the authorized installer currently has in service,~~
   ~~b. The number of certified ignition interlock devices installed since the previous monthly report,~~
   ~~c. The number of pending installations, and~~
   ~~d. The number of certified ignition interlock devices removed by the authorized installer since the previous monthly report.~~
2. A manufacturer shall ensure that its authorized installer mails, faxes, or e-mails to the Division, by the 10th day of January, April, July, and October, a quarterly report containing the following information for the previous three months:
   a. The number of certified ignition interlock devices the authorized installer currently has in service;
   b. The number of certified ignition interlock devices installed since the previous quarterly report; and
   c. The number of certified ignition interlock devices removed by the authorized installer since the previous quarterly report.

**C.** Periodic ~~audits~~ inspections. The Division shall periodically conduct an ~~audit~~ inspection at the premises of ~~an~~ a manufacturer or its authorized installer, ~~or manufacturer, in accordance with~~ under A.R.S. § 41-1009 and R17-5-613. The ~~audit~~ inspection shall determine ~~the following:~~ whether the manufacturer, its authorized installer, the service center of the authorized installer, and the installer-certified service representatives are in compliance with this Article and Article 7.

~~1. Whether the authorized installer or manufacturer retains records in accordance with subsection (A),~~
~~2. Whether the authorized installer maintains adequate supplies of a warning label conforming to the warning label design adopted by the Division, and~~
~~3. Whether the authorized installer maintains adequate supplies of the written instructions provided to participants and other operators of a vehicle equipped with a certified ignition interlock device.~~

**R17-5-613. Ignition Interlock Investigator**

**A.** The Division's ignition interlock investigator shall investigate any complaint or report of misconduct brought against a certified ignition interlock device manufacturer, installer, service center, or installer-certified service representative for noncompliance with a provision of Articles 6 or 7 of this Chapter or A.R.S. Title 28, Chapter 4, Article 5.

**B.** Inspection of a manufacturer, installer, or service center under Articles 6 or 7 of this Chapter shall be conducted in accordance with A.R.S. § 41-1009. The inspection shall include an examination of participant records and verification of an adequate supply of the warning labels and written instructions required to be made available under A.R.S. § 28-1462, R17-5-609, and R17-5-704.

**C.** The Division's ignition interlock investigator shall perform onsite inspections of a manufacturer, installer, or service center as needed to verify continuous compliance with the Division's ignition interlock program requirements established under Articles 6 and 7 of this Chapter and A.R.S. Title 28, Chapter 4, Article 5.

## ARTICLE 7. ~~REPEALED~~ IGNITION INTERLOCK DEVICE INSTALLERS

**R17-5-701. ~~Repealed~~ Definitions**

In addition to the definitions under A.R.S. § 28-1301, and unless the context otherwise requires, the definitions under A.A.C. R17-4-408 and R17-5-601 apply to this Article.

**R17-5-702. ~~Repealed~~ Ignition Interlock Device Installer Certification; Application Requirements**

**A.** A manufacturer's authorized installer shall be certified by the Division before installing a certified ignition interlock device under Arizona law.

**B.** A manufacturer's authorized installer shall obtain from the manufacturer, as provided under R17-5-609, all necessary training and skills required to install, troubleshoot, examine, and verify proper operation of the manufacturer's certified ignition interlock device.

**C.** A manufacturer's authorized installer shall submit to the Division a properly completed application for installer certification. The application for installer certification shall provide:

1. The authorized installer's name;
2. The authorized installer's business address and telephone number;
3. The authorized installer's status as a sole proprietorship, partnership, limited liability company, or corporation;
4. The name of the sole proprietor or of each partner, officer, director, manager, member, agent, or 20% or more stockholder;
5. The name and model number of each certified ignition interlock device the authorized installer intends to install; and
6. The following statements, signed by the authorized installer and acknowledged by a notary public or Division agent:
   a. A statement that all information provided on the application form, including all information provided on any attachment to the application form, is complete, true, and correct;
   b. A statement that the authorized installer agrees to indemnify and hold harmless from all liability the state of Arizona and any department, division, agency, officer, employee, or agent of the state of Arizona;
   c. A statement that the authorized installer agrees to comply with all requirements under this Article; and
   d. A statement that the authorized installer agrees to immediately notify the Division of any change to the information provided on the application form.

**D.** The Division shall process an application for installer certification as provided under R17-5-605.

**E.** Division certification issued to an authorized installer under this Article shall not expire as long as the installer remains authorized by a manufacturer to install its certified ignition interlock device model under Arizona law.

1. If a Division-certified installer is no longer authorized by a manufacturer to install its certified ignition interlock device, the installer's certification is immediately expired.
2. If the installer again becomes authorized by a manufacturer to install its certified ignition interlock device, the installer may reapply to the Division for certification under this Article by submitting a new application.

**F.** A Division-certified ignition interlock device installer shall notify the Division within 24 hours of making a decision to relocate a fixed-site service center.

**G.** A Division-certified ignition interlock device installer shall train and certify each of its service representatives on the proper installation of a certified ignition interlock device before allowing the service representative to install the certified ignition interlock device.

**H.** A Division-certified ignition interlock device installer shall provide to the Division a current list of the names of each of its certified service representatives. The installer shall electronically notify the Division within 24 hours of making a change to its list.

~~**R17-5-703. Repealed**~~

**~~R17-5-610.~~R17-5-703. Ignition Interlock Device Installer Bond Requirements**

~~**A.** The amount of the ignition interlock installer bond is $25,000.~~

~~**B.** Exhibit A Ignition Interlock Installer Bond and Exhibit B Ignition Interlock Installer Bond, which follow this Section, are the approved bond forms.~~

~~**C.** Before installing, servicing, or removing a Division-certified ignition interlock device, an installer shall:~~

~~1. Be appointed by a manufacturer as an authorized installer of an ignition interlock device model certified by the Division or for which the manufacturer seeks certification;~~
~~2. Obtain an ignition interlock installer bond in the approved form from a surety company authorized by the Arizona Department of Insurance to do general surety business in Arizona; and~~
~~3. Submit the original completed Exhibit A or Exhibit B to the Arizona Department of Transportation, Motor Vehicle Division, Enforcement Services, 2500 West Broadway Road, Tempe, Arizona 85282.~~

~~**D.** An installer shall maintain an ignition interlock installer bond in an approved form while installing, servicing, or removing Division-certified ignition interlock devices.~~

~~**E.** An installer appointed to install, service, or remove more than one certified ignition interlock device model needs only one bond.~~

**A.** Before installing, servicing, or removing a certified ignition interlock device, an installer shall:
1. Be appointed by a manufacturer as an authorized installer of its certified ignition interlock device;
2. Obtain an ignition interlock installer bond from a surety company authorized by the Arizona Department of Insurance to conduct general surety business in Arizona. The ignition interlock installer bond shall be:
   a. In the amount of $25,000;
   b. On the approved form provided by the Division; and
   c. Maintained for as long as the installer intends to install, service, or remove Division-certified ignition interlock devices under Arizona law;
3. Submit the original completed ignition interlock installer bond to the Arizona Department of Transportation, Motor Vehicle Division, Ignition Interlock Program, 1801 W. Jefferson St. MD530M, Phoenix, AZ 85007; and
4. Receive Division certification under R17-5-702.

**B.** An installer authorized by a manufacturer and certified by the Division to install, service, or remove more than one certified ignition interlock device model needs only one bond.

**Exhibit A.** ~~**Ignition Interlock Installer Bond**~~ **Repealed**

M • V • D
MOTOR VEHICLE DIVISION
ARIZONA DEPARTMENT OF TRANSPORTATION

Enforcement Services
Motor Vehicle Division
2500 W Broadway Rd
Tempe AZ 85282

96-0196 R07/99

## IGNITION INTERLOCK INSTALLER BOND

Bond Number

| Principal Name (Ignition Interlock Device Installer) | Business Type ☐ Individual ☐ Partnership ☐ Corporation | |
|---|---|---|
| Trade Name/Doing Business As | Business Location City | State |
| Surety Name | | Surety State |

The Surety named above, a corporation duly organized and existing under and by virtue of the laws of the Surety State named above and duly authorized by the Arizona Department of Insurance under the laws of the State of Arizona to do a general surety business in the State of Arizona, and the Principal named above give this bond to the State of Arizona, as Obligee.

**Recitals** Principal and Surety jointly and severally bind themselves, their successors, assigns, and legal representatives to the Obligee in the sum of $25,000.

1. The sum stated above establishes the limit of Surety's liability at any time after the effective date of the bond.
2. Principal is a manufacturer-appointed installer of ignition interlock devices certified by the Arizona Department of Transportation, Motor Vehicle Division (MVD).

**Duration** This bond becomes effective on the date of device certification or upon the execution of this document, whichever occurs last. This bond shall remain in effect until terminated by Surety as follows: Surety may terminate liability under this bond if surety gives 60 days written notice to the MVD Director of the intent to terminate liability. Written notice shall be delivered to MVD at the address above. Termination of liability occurs on the last day of the month that includes the end of the 60-day period. If a new bond is filed by the Principal and accepted by the MVD Director, termination of liability under this bond occurs on the effective date of the new bond. The Surety shall remain fully liable for acts or omissions of the Principal before termination of liability.

**Condition of Obligation** Principal shall make monetary payment in compensation to any person ordered by an Arizona court to equip a motor vehicle with a certified ignition interlock device and who suffers loss from:

1. Insolvency or discontinuance of business of Principal, or
2. Noncompliance of Principal or Principal's agent with the administrative rules made under ARS 28-1462.B.

**Venue** Any action or proceeding in connection with this bond or the obligations arising under this bond shall be brought in Maricopa County, Arizona.

**Severability** If a court of competent jurisdiction finds any provision of this bond unenforceable, all other provisions of this bond shall remain in effect.

The Principal and Surety executed this bond on _____.

A power of attorney must be attached designating the Surety Attorney-In-Fact.

| Surety Attorney-in-Fact Name | Principal or Duly Authorized Officer Name | Signature |
|---|---|---|
| Phone ( ) | Partner Name | Signature |
| Signature | Partner Name | Signature |

| Surety Resident Agent Name | Title | Send Bond Claims To |
|---|---|---|
| Mailing Address | | Mailing Address |
| City, State, Zip Code | | City, State, Zip Code |
| Signature | Phone ( ) | Phone ( ) |

**Exhibit B.** ~~Ignition Interlock Installer Bond~~ Repealed

ADOT | **Motor Vehicle Division**

Enforcement Services
Motor Vehicle Division
2500 W Broadway Rd
Tempe AZ 85282

96-0196 R06/00

## IGNITION INTERLOCK INSTALLER BOND

| Bond Number | |
|---|---|

| Principal Name (Ignition Interlock Device Installer) | Business Type ☐ Individual ☐ Partnership ☐ Corporation |
|---|---|

| Trade Name/Doing Business As | Business Location City | State |
|---|---|---|

| Surety Name | Surety State |
|---|---|

The Surety named above, a corporation duly organized and existing under and by virtue of the laws of the Surety State named above and duly authorized by the Arizona Department of Insurance under the laws of the State of Arizona to do a general surety business in the State of Arizona, and the Principal named above give this bond to the State of Arizona, as Obligee.

**Recitals** Principal and Surety jointly and severally bind themselves, their successors, assigns, and legal representatives to the Obligee in the sum of $25,000.

1. The sum stated above establishes the limit of Surety's liability at any time after the effective date of the bond.
2. Principal is a manufacturer-appointed installer of ignition interlock devices certified by the Arizona Department of Transportation, Motor Vehicle Division (MVD).

**Duration** This bond becomes effective on the date of device certification or upon the execution of this document, whichever occurs last. This bond shall remain in effect until terminated by Surety as follows: Surety may terminate liability under this bond if surety gives 60 days written notice to the MVD Director of the intent to terminate liability. Written notice shall be delivered to MVD at the address above. Termination of liability occurs on the last day of the month that includes the end of the 60-day period. If a new bond is filed by the Principal and accepted by the MVD Director, termination of liability under this bond occurs on the effective date of the new bond. The Surety shall remain fully liable for acts or omissions of the Principal before termination of liability.

**Condition of Obligation** Principal shall make monetary payment in compensation to any person ordered by an Arizona court to equip a motor vehicle with a certified ignition interlock device and who suffers loss from:

1. Insolvency or discontinuance of business of Principal, or
2. Noncompliance of Principal or Principal's agent with the administrative rules made under ARS 28-1462.B.

**Venue** Any action or proceeding in connection with this bond or the obligations arising under this bond shall be brought in Maricopa County, Arizona.

**Severability** If a court of competent jurisdiction finds any provision of this bond unenforceable, all other provisions of this bond shall remain in effect.

The Principal and Surety executed this bond on _____.

A power of attorney must be attached designating the Surety Attorney-In-Fact.

| Surety Attorney-In-Fact Name | Principal or Duly Authorized Officer Name | Signature |
|---|---|---|
| Phone ( ) | Partner Name | Signature |
| Signature | Partner Name | Signature |

| Surety Resident Agent Name | Title | Send Bond Claims To |
|---|---|---|
| Mailing Address | | Mailing Address |
| City, State, Zip Code | | City, State, Zip Code |
| Signature | Phone ( ) | Phone ( ) |

**R17-5-704. ~~Repealed~~ Division-certified Installer Responsibilities**

An authorized installer certified by the Division to install a certified ignition interlock device shall:

1. Follow the installation and operating procedures established, and provided, by the manufacturer;
2. Acquire and maintain all necessary training and skills specified by the manufacturer for installing, troubleshooting, examining, and verifying the proper operation of its certified ignition interlock device;
3. Comply with all of the manufacturer's procedures for removing the certified ignition interlock device from a vehicle;
4. Electronically notify the Division within 24 hours after removing a certified ignition interlock device under R17-5-611;
5. Provide to the manufacturer, or to the Division if delegated by the manufacturer, an accurate electronic reporting of all applicable information required of the manufacturer under R17-5-610;
6. Provide to every participant, and make available for every person operating a motor vehicle equipped with the certified ignition interlock device, a copy of the manufacturer's written instructions for the following:
   a. Operating a motor vehicle equipped with the certified ignition interlock device;
   b. Cleaning and caring for the certified ignition interlock device; and
   c. Identifying and addressing vehicle malfunctions or repairs that may affect the certified ignition interlock device;
7. Ensure that each participant receives an operator's manual and is further instructed regarding all of the following:
   a. How to use the system;
   b. How to obtain service for the system;
   c. How to find answers to any additional questions;
   d. How the alcohol retest feature works;
   e. How drinking alcohol before a test may result in a reading of sensitive or fail;
   f. How the handset of the device shall not be removed, except by an installer-certified service representative;
   g. How missing an appointment for a regularly scheduled accuracy check will cause the certified ignition interlock device to enter into a lock-out condition that will emit a unique cue, either auditory, visual, or both, to warn the driver that after 72 hours the vehicle will not start. It shall be the responsibility of each participant to have the car towed to the service center if a lock-out condition occurs;
   h. How noncompliance with a regularly scheduled accuracy check shall result in suspension of the participant's driver license until proof of compliance is submitted to the Division under A.R.S. § 28-1463; and the duration of the participant's certified ignition interlock device requirement shall be extended under A.R.S. § 28-1464 and A.A.C. R17-4-408;
   i. What the penalties are for tampering with, circumventing, or misusing the system;
   j. What will happen after failing a start-up breath alcohol test; and
   k. What will happen after failing a rolling retest.
8. Ensure that each participant demonstrates:
   a. A properly delivered alveolar breath sample; and
   b. An understanding of how the abort test feature works.
9. Affix conspicuously, the warning label provided by the Manufacturer under R17-5-609.
10. Check each device for evidence of tampering at least once every 60 days or more frequently if needed. This anticircumvention check shall be conducted at each participant's regularly scheduled accuracy and compliance check required under R17-5-610.
11. Notify the Division electronically under R17-5-610 if any evidence of tampering is discovered.

**R17-5-705. ~~Repealed~~ Installer-certified Service Representatives**

**A.** Initial certification.

1. To achieve certification as a service representative, an individual shall obtain written documentation from a Division-certified ignition interlock device installer documenting that the individual is currently trained in each aspect involved with the specific certified ignition interlock device for which the individual seeks certification to install or service.
2. An installer shall not certify as a service representative, any individual with a felony conviction in the five years preceding the individual's request for certification. In this Section, conviction means that a court of competent jurisdiction adjudicated the individual guilty.
3. The Division, with advance notice to the installers, may require additional standards for installer certification of its service representatives when needed to ensure compliance with the Division's ignition interlock program.

**B.** Proficiency requirements.

1. It is the responsibility of the installer to ensure that its certified service representatives maintain proficiency in each aspect involved with each specific certified ignition interlock device model the individual is certified to install or service.
2. The Division's ignition interlock investigator may at any time require an installer-certified service representative to demonstrate competency in the installation, inspection, downloading, calibrating, repairing, monitoring, maintaining, servicing or removal of a specific certified ignition interlock device. A failure of the installer-certified service repre-

sentative to demonstrate proficiency to the Division's ignition interlock investigator may result in disciplinary action against the installer as provided under R17-5-707.

**R17-5-706. ~~Repealed~~ Accuracy and Compliance Check; Requirements**

**A.** An installer-certified service representative shall inspect, maintain, and check each certified ignition interlock device for calibration accuracy and operational performance before the device is placed into, or returned to, service.

**B.** The installer-certified service representative shall perform each accuracy and compliance check in accordance with NHTSA specifications at a service center authorized by the installer and certified by the Division under R17-5-707.

**C.** The accuracy and compliance check performed under R17-5-610 shall include an inspection of the device to verify that it is properly functioning in accordance with all of the following criteria:

1. Accuracy standards as prescribed under R17-5-603;
   a. The device shall be calibrated before placed into, or returned to, service.
   b. The device shall be subjected to a calibration test before returning it to service. This test shall consist of introducing to the device a known alcohol concentration from a reference sample device, the analysis of which indicates the device's agreement with the known concentration. The installer's software shall be capable of performing, documenting, and reporting the result of this calibration test. The test result described herein shall verify the accuracy of the ignition interlock device according to the standards prescribed under R17-5-603; and
2. Anticircumvention standards and operational features as prescribed under R17-5-603.

**D.** The calibration test referenced under subsection (C)(1) shall be performed when the information uploaded from a device indicates that the device has experienced an interruption in service or was completely disconnected. Additionally, the complete device shall be examined for evidence of tampering and circumvention while it is still attached to the vehicle.

**E.** If calibration confirmation test results reveal that the device is not properly calibrated, the device shall be recalibrated to restore the accuracy standards prescribed under R17-5-603 before the device is returned to service.

**F.** If at any time an individual device fails to meet the provisions of this Section, the manufacturer, installer, service center, or installer-certified service representative shall either:

1. Repair, recalibrate, and retest the device to ensure that it does meet all applicable standards; or
2. Remove the device from service.

**R17-5-707. Certification and Inspection of Service Centers; Application**

**A.** A service center, whether located on a fixed site or mobile, shall be approved and certified by the Division under this Article before it is used by an installer to conduct certified ignition interlock device related business in this state.

**B.** For Division approval and certification of a service center, an installer shall submit to the Division a separate application for each individual service center the installer intends to use for conducting certified ignition interlock device related business in this state.

**C.** On an application for the approval and certification of a service center, available from the Division, an installer shall identify:

1. The physical location of the service center;
2. The ignition interlock device, or devices, to be merchandised and serviced at the location; and
3. The reference sample device, or devices, that will be used at the location.

**D.** An installer shall attach, to the application submitted to the Division under subsection (B), a statement from the manufacturer acknowledging that the installer is authorized to install the certified ignition interlock device, or devices, described on the application.

**E.** An installer applying for Division approval and certification of a service center shall agree to:

1. Allow the Division access to the service center for inspection under subsection (G); and
2. Comply with all provisions under this Article and A.R.S. Title 28, Chapter 4, Article 5.

**F.** For Division approval and certification of a service center, the installer's ignition interlock device testing facilities, equipment, and the procedures used in the service center shall meet the following conditions:

1. A fixed-site service center shall be located in a facility that properly and successfully accommodates installing, inspecting, downloading, calibrating, repairing, monitoring, maintaining, servicing, and removing a specific ignition interlock device. The installer shall:
   a. Provide a designated waiting area for the participant that is separate from the installation area; and
   b. Ensure that no participant witnesses installation of the certified ignition interlock device.
2. A mobile service center shall be equipped with the same materials and capacities prescribed under subsection (1). An installer or service representative operating a mobile service center shall:
   a. Designate a waiting area for the participant that is separate from the area used for the installation; and
   b. Ensure that no participant witnesses installation of the certified ignition interlock device.
3. The installer, whether operating a fixed-site service center, or mobile, shall ensure that its certified service representatives utilize all of the following:
   a. The analysis of a reference sample such as headspace gas from a mixture of water and alcohol, the results of which shall agree with the reference sample predicted value, or other methodologies approved by the Division.

The preparatory documentation on the reference sample solution, such as a certificate of analysis, shall be made available to the Division upon request.

b. The startup set point value established under R17-5-603. All analytical results shall be expressed in grams of alcohol per 210 liters of breath (g/210L).

c. The most current versions of manufacturer software and firmware to ensure continuous compliance under this Article and A.R.S. Title 28, Chapter 4, Article 5.

4. Only a properly trained installer-certified service representative shall perform certified ignition interlock device related services rendered through a service center.
   a. The installer shall maintain sufficient staff at each service center to ensure an acceptable level of service. The service center shall always be staffed with at least one certified service representative.
   b. The installer shall schedule accuracy and compliance checks at each service center in a manner that will not deprive a participant of an acceptable level of service.
   c. The installer's software shall document the certified service representative performing each accuracy and compliance check and shall record the date each service is performed.
   d. Division-certified installers may train potential certified service representatives in the service center only under the direct supervision of a currently certified service representative.
5. The installer shall agree to:
   a. Submit a violation to the Division as prescribed under R17-5-610 no later than 24 hours after the installer discovers the violation;
   b. Maintain complete records of each device installation for five years from the date of its removal;
   c. Require each applicant seeking installer certification as a service representative to certify that he or she has not been convicted of a felony within the five years preceding the date of application;
   d. Retain the five-year felony certification required of each installer-certified service representative under subsection (c) for five years after the date of the employee's separation from employment; and
   e. Make available to the Division upon request, either by inspection or in hardcopy form, all records relating to the installer's ignition interlock device operations.
6. The installer shall ensure that all anticircumvention features are activated on each installed certified ignition interlock device.
7. The installer shall install and inspect each certified ignition interlock device as provided under this Article.
   a. Each time an installer uploads the information from a participant's certified ignition interlock device, the installer-certified service representative shall perform a visual inspection of the vehicle, the device, and the device's wiring to ensure no tampering or circumvention has occurred during the monitoring period.
   b. The calibration test referenced under R17-5-706 shall be performed if the downloaded device information indicates that the device has experienced an interruption in service or was completely disconnected.
8. The installer shall agree to abide by conditions for the removal of an ignition interlock device, including but not limited to the following:
   a. No ignition interlock device shall be removed without notifying the Division of the removal under R17-5-610.
   b. A service representative or service center shall not remove the certified-ignition interlock device of another manufacturer, except in an emergency, or other special circumstance authorized by the Division. All such removals shall be documented and reported to the Division. All device removal records shall be retained as prescribed under R17-5-612.
   c. When a participant requests to exchange one manufacturer's device for the device of another manufacturer, the installer of the original device shall notify the Division of the device removal under R17-5-610.

**G.** The Division may cancel the certification of an installer or its service center if the installer or service center is found to be operating in violation of any provision under this Article or A.R.S. Title 28, Chapter 4, Article 5. To ensure continuous compliance with all provisions under this Article and A.R.S. Title 28, Chapter 4, Article 5, the Division's ignition interlock investigator may inspect an installer's service center under A.R.S. § 41-1009.

**H.** An installer shall designate a custodian of records who shall, if required in an administrative hearing or court proceeding, provide testimony concerning the interpretation of data storage system records and answer questions concerning the installer's certification and compliance with the Division's ignition interlock program requirements.

**I.** Before issuing certification, the Division may perform an onsite evaluation of a service center to verify compliance with this Article.

**J.** After verifying compliance with subsections (A) through (F), the Division shall issue a certificate to the installer and each service center that shall remain valid until cancelled by the Division or terminated by the installer or service center. Issuance of a certificate to an installer or service center under this Section shall be evidence that the installer's service center has met all of the criteria necessary for approval and certification by the Division.

**K.** Certification of the installer's service center is contingent upon the installer's agreement to conform with and abide by all directives, orders, and policies issued by the Division regarding any service center activities regulated by the Division under this Article and A.R.S. Title 28, Chapter 4, Article 5, which may include:

1. Program administration;
2. Reports;
3. Records and forms;
4. Inspections;
5. Methods of operations and testing protocol;
6. Personnel training and qualifications;
7. Criminal history considerations for installer-certified service representatives; and
8. Records custodian.

**L.** Certification issued under this Section may be cancelled by the Division if the installer, service center, or installer-certified service representative violates or is not in compliance with a provision of this Article or A.R.S. Title 28, Chapter 4, Article 5, or the certified ignition interlock device equipment it is authorized by the manufacturer to install no longer meets the requirements provided under Article 6 of this Chapter.

**R17-5-708. Cease and Desist; Denial or Cancellation of Certification; Appeal; Hearing**

**A.** If the Director has reason to believe that a Division-certified installer or service center is operating in violation of a provision under this Article or A.R.S. Title 28, Chapter 4, Article 5, the Director shall immediately issue and serve a cease and desist order on the installer or service center by personal delivery or by mail to its last known address.
1. On receipt of a cease and desist order, an installer or service center shall immediately take action as specified in the order or cease and desist from engaging in any further activity authorized under this Article or A.R.S. Title 28, Chapter 4, Article 5.
2. On failure of an installer or service center to comply with a cease and desist order, the Director shall issue an immediate cancellation of its installer or service center certification.

**B.** Appeal of a denial of application or cancellation of certification. If the Division denies a pending application for certification, or cancels a certification previously issued to an installer or its service center, the installer or service center may appeal the action as follows:
1. Within 15 days after receipt of a notice of denial of application or a notice of cancellation of certification, the installer or service center may file a written request for a hearing on the issue of the denial or cancellation with Division's Executive Hearing Office as prescribed under 17 A.A.C. 1, Article 5.
2. If a hearing on the issue of the denial or cancellation is timely requested, the Division's Executive Hearing Office shall conduct the hearing as prescribed under A.R.S. Title 41, Chapter 6, Article 6, and 17 A.A.C. 1, Article 5. The request for a hearing stays the summary cancellation of an installer or service center's certified activities.
3. Within 10 days after a hearing, the Hearing Officer shall issue to the installer or service center a written decision, which shall:
   a. Provide findings of fact and conclusions of law; and
   b. Grant the application, deny the application, or cancel the certification.
4. If the Hearing Officer affirms the denial of application or cancellation of certification, the installer or service center may seek judicial review under A.R.S. Title 12, Chapter 7, Article 6, within 30 days from the date of the decision and order. The denial of application or order of cancellation shall not be suspended during pendency of an appeal.

**C.** After denial of an application, or cancellation of a certification, an installer or service center may reapply to the Division for a new certification by completing a new application and meeting all certification requirements under this Article. A cancellation does not prohibit a manufacturer, installer, or service center from submitting a subsequent application for certification if all certification requirements are met.